COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS

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I hereby declare that the thesis entitled **"COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS"** submitted towards partial fulfillment of the requirements for the award of **MD ANAESTHESIOLOGY** degree to BFUHS is a compilation of original work carried out by me under the supervision of **Dr. Kamakshi Garg,** Professor, Department of Anaesthesiology, **Dr. Mirley Rupinder Singh**, Professor, Department of Anaesthesiology. No part of this thesis has formed the basis for the award of any degree previously.

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TO

MY FAMILY &

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"WILL IS THE INSTRUMENT OF GOD WITHIN US. IN WILL, LIES HIS LIMITLESS POWER THAT CONTROLS ALL FORCES OF NATURE. THE POWER IS OURS TO BRING ABOUT WHATEVER WE DESIRE". First and foremost, I sincerely want to thank ALMIGHTY GOD for all His blessings, giving me His will, wisdom, strength and determination to pursue the degree and complete this thesis.

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Dr. Sameera Kohli

LIST OF ABBREVIATIONS

%	Percentage
ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
cm	Centimetre
cm H2O	Centimetres of water
CO2	Carbon dioxide
DBP	Diastolic Blood Pressure
ECG	Electrocardiography
EtCO2	End tidal carbon dioxide
ETT	Endotracheal tube
FRC	Functional Residual Capacity
GA	General Anaesthesia
HR	Heart Rate
i.e	That is
i.v.	Intravenous
ICU	Intensive Care Unit
inj	Injection
IOP	Intraocular pressure
Kg	Kilogram
L	Litre
LMA	Laryngeal mask airway
m^2	Metre square
mcg	Microgram
mg	Milligram
min	Minutes
ml	Millilitres
mmHg	Millimetre of mercury
NIBP	Non Invasive Blood Pressure
NPO	Nil per os
NRS	Numerical Rating Scale
OLP	Oropharyngeal leak pressure

OR	Operating Room
PaCO2	Partial Pressure of arterial carbon dioxide
PVC	Polyvinyl chloride
SAD	Supraglottic airway device
SBP	Systolic Blood Pressure
SD	Standard deviation
SpO2	Oxygen saturation
WHO	World Health Organisation

ABSTRACT

Introduction- Supraglottic airway devices (SADs) have been used for routine airway management and maintenance during anaesthesia in patients without increased risks for aspiration of gastric contents. SADs offer an alternative airway to traditional tracheal intubation with potential benefits, including ease of fitness and less airway disturbance. Morbidly obese patients are at risk of difficult mask ventilation as well as intubation. Airway of these patients is a major concern for an anaesthesiologist while providing general anaesthesia. SADs act as a useful alternative in obese patients.

Aims and objectives- To compare oropharyngeal leak pressures as a measure of successful placement of I-Gel and Ambu AuraGain LMA in obese patients undergoing laparoscopic surgeries.

Materials and methods- A randomized controlled comparative study was conducted in 50 obese patients undergoing laparoscopic surgeries. In group A, Ambu Auragain was inserted and in group I, I-Gel LMA was inserted and they were compared with respect to oropharyngeal leak pressures.

Results- The mean oropharyngeal leak pressures of Group I before pneumoperitoneum was 22.36 ± 4.02 cm of H2O and that of Group A was 21.76 ± 4.26 cm of H2O (p value being 0.640) . The mean OLP of Group I after pneumoperitoneum was 26.92 ± 4.41 cm of H2O and that of Group A was 26.38 ± 3.83 cm of H2O (p value being 0.725). The OLP before and after pneumoperitoneum of both the groups were comparable. Also time of insertion, number of attempts required for insertion, ease of insertion of LMA, manipulations required for adjustment of LMA were comparable in both the groups.

Conclusion- I-Gel and Ambu AuraGain are comparable and equally effective to secure airway in obese patients for laparoscopic surgeries without increasing the risk of aspiration with no significant difference in time and ease of insertion, manipulations required to adjust LMA and postoperative complications.

Keywords- Supraglottic Airway Devices, Laparoscopic surgeries, Obese, Oropharyngeal leak pressures.

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INTRODUCTION

Obesity accounts for 11% of world's total population according to WHO and is becoming increasingly prevalent by the day. Obesity is a multisystem disease involving many organs. It is a known risk factor, associated with many complications in anaesthesia, including difficult airway. Early identification of such situations and patients, who are at increased risk for airway complications is a crucial part of anaesthesia and a key to optimal care. Any difficulty in tracheal intubation will lead to rise in morbidity and mortality associated with anaesthesia. Hence, obese patient's airway becomes a major priority for an anaesthesiologist securing definitive airway in ICU or while administering general anaesthesia. [1,2]

Obesity is associated with anatomical and physiological difficult airway. Anatomically, obese patients tend to have short and thick neck causing limited neck movement. There is restriction of atlanto-axial joint movement and cervical spine mobility by lower cervical and upper thoracic fat pads in these patients, hence further contributing to limited neck movement, leading to difficult airway. The excessive fatty tissue deposited in oral cavity may go unnoticed during routine preanaesthetic check-up. They have posterior cervical, suprasternal and presternal accumulation of adipose tissue and a thick fat pad in submental area. Moreover in such patients large tongue and increased oropharyngeal soft tissue restrict the movement of the laryngoscope. All the above factors add to challenging bag and mask ventilation, difficult laryngoscopy and endotracheal intubation. The increased soft tissue mass around the neck of such patients make them prone to early airway obstruction with the loss of consciousness during induction of anaesthesia, leading to early desaturation and decreased time for tracheal intubation. [3-5]

Physiologically, the increased body mass leads to increased metabolism of adipose tissue, further leading to increased oxygen

consumption in body and increased carbon dioxide production. Due to increased body mass and heavy chest wall, there is reduced chest wall compliance (up to 30%). The reduction in compliance and increased work of breathing leads to additional stress response of the patient above surgical stress. On top of increased work of breathing, the functional residual capacity (FRC) decreases with increase in BMI. Hence these patients are prone to hypoxia even while they are conscious and tend to desaturate rapidly once apnoeic as their oxygen reserve is reduced (reduced FRC), and oxygen consumption and demand increased, thus adequate pre-oxygenation and securing early definitive airway becomes a priority in such patients. [3-5]

The worst-case scenario happens with a difficult airway in which both ventilation and intubation are difficult. This predisposes them to multiple episodes of rapid desaturation during airway management, especially during laryngoscopy and endotracheal intubation. In that dreadful situation, the laryngeal mask airway (LMA) acts as a rescue device for anaesthesiologist to secure airway. [4]

The gold standard method to secure airway in any patient, especially obese patients, is endotracheal intubation; but the difficulty associated with bag and mask in such patients, during laryngoscopy and intubation, results in increased time or multiple attempts at laryngoscopy, leading to altered and raised fluctuations in haemodynamic stress response and higher incidence of dysphonia, sore throat, hoarseness and dysphagia in post-operative period. [6-8]

As a solution to above complications, an alternative to endotracheal intubation, a second generation supraglottic airway device (SADs) are useful in managing difficult airway scenarios, where they are used to deliver oxygen and can also act as a guide for insertion of ETT in situations of difficult or failed intubation. These are also used as rescue devices in cases of difficult and challenging bag and mask ventilation.[9] Nowadays these devices are gaining importance among

anaesthesiologists and have proved advantageous in obese patients because of their ease of insertion followed by higher rates of successful insertion in first attempt, thus reducing the number of episodes of desaturation and lesser fluctuations in hemodynamic stress response to laryngoscopy. [6-8]

Studies talk in favour of the SADs in terms of their use in difficult airways, safety profile, ease of insertion, complications, recovery of patients and cost analyses. Studies have shown that SADs can be used in obese patients without fear of major airway related complications. Nowadays, SADs form an integral part of difficult airway cart. SADs can function as life saving devices in obese patients and can be a saviour in difficult airway settings. [9-11] They function as a connecting link between bag and mask ventilation and endotracheal intubation in case of emergency or difficult airway management.

Despite various benefits offered by SADs, there are certain drawbacks of the same, including increased risk of gastric regurgitation and aspiration, incomplete insertion, inadequate ventilation, risk of laryngospasm and bronchospasm associated with SADs.[10] Moreover the volume and acidity of gastric components is often increased in obese individuals. Thus the risk of aspiration is always there in these patients. They have a larger residual volume of gastric components still remaining in stomach, even after a strict NPO (nil-per-os) period. Moreover, the need of high ventilation pressures during possible difficult facemask ventilation in obese individuals makes such patients susceptible to regurgitation and thereby increasing risk of aspiration. The LMA is often avoided in obese population due to higher risk for pulmonary aspiration associated with increased intraabdominal pressure. [3,4]

Over a period of time, new modifications were done in classic LMA model to include second tube placement, lateral to the airway channel to facilitate passage of nasogastric tube, in order to create separate

respiratory & oesophageal channels & permit easy escape of gastric contents to reduce risk of gastric insufflation, regurgitation & pulmonary aspiration. First generation LMAs can lead to higher incidences of pulmonary aspiration in obese patients. Second generation LMAs offer functional separation of the respiratory & digestive pathways, better access of airway, high leakage pressure, optimal fit of the airway device & dual gastric ports. [12]

Oropharyngeal leak pressure (OLP) is a measurable criteria that is used to access safety and compare efficacy of SADs. A higher OLP means that leak for that particular supraglottic airway device will occur at higher airway pressures. In other words, a higher OLP ensures there is better seal between the underlying mucosa and the SAD as compared to poor seal in lower OLP. This protects against gastric aspiration. Higher OLPs are preferred in obese patients, increased intra-abdominal pressure such as in laparoscopic surgeries and in patients presenting with restrictive lung diseases. [13]

Newer SADs are designed to achieve higher OLPs, increase gastric venting and allows SAD-guided intubations. Various such models are : LMA Proseal, LMA Supreme, AuraGain, I-Gel etc. [14]

A new variant of LMA – " I-gel " (Intersurgical Ltd, Wokingham, Berkshire) developed in 2007 [6,8] , having a soft gel like cuff made of thermoplastic elastomer (styrene ethylene butadyiene styrene), which is soft, transparent, gel like & designed to anatomically fit the perilaryngeal & hypolaryngeal structures, without any inflatable cuff.[15,16]

Ambu AuraGain (Ambu, Ballerup, Denmark) is a second generation novel cuffed SGA introduced in 2015, made of polyvinyl chloride (PVC), which has a preformed curve, bite block & also a built in gastric port. [4] It has the capability of working as a guide for intubation. The airway tube of AuraGain is broader, thereby accommodating comparatively bigger Endotracheal Tube (ETT). [17,18] It

also has a thin and soft cuff which helps in providing a good seal thus preventing gastric regurgitation and aspiration.[19] Studies have shown that Ambu AuraGain has high oropharyngeal seal pressure and easier gastric tube insertion making it suitable for use with positive pressure ventilation.

In this randomised study, we compared two Supraglottic Airway Devices, namely, I-Gel and Ambu AuraGain, with respect to, oropharyngeal leak pressures, and to find out which one consumes less time for insertion, maintaining optimal haemodynamics and minimum drop in saturation while securing obese patients' airway.

AIMS AND OBJECTIVES

To compare oropharyngeal leak pressures as a measure of successful placement of I-Gel and Ambu AuraGain LMA in obese patients undergoing laparoscopic surgeries.

REVIEW OF LITERATURE

Obesity is defined as a disorder in which excessive body fat accumulates in patient's body to the extent that it may have an adverse effect on patient's physical, mental and emotional well-being, leading to decreased life expectancy and/or increased health problems. [5]

Obesity is measured by certain indices which include - Ideal body weight, which is measured as height (in cm) – x (x is 100 for adult males and 105 for adult females). An individual is said to be obese if his weight exceeds 20% of ideal body weight. [5]

Obesity is also defined by criteria of Body Mass Index (BMI) or 'Quetelet Index'. It can be calculated by dividing the patient's weight in kilograms by their height in metres square (kg/m^2). Classification and grading of BMI according to WHO Criteria is as follows: [5]

Table 1: Classification and BMI Grading according to WHO Criteria

BMI	**CATEGORY**
< 18.5	Underweight
18.5–24.9	Normal weight
25.0–29.9	Overweight
30.0–34.9	Class I Obesity
35.0–39.9	Class II Obesity
≥ 40.0	Class III Obesity
≥ 40– 49.9	Morbid Obesity
≥ 50	Super Obesity

Obesity accounts for 11% of world's total population according to WHO and is becoming increasingly prevalent by the day. Thus obese patients will form a major constituent of the surgical population in coming years. The number of obese patients who stand in need of

general anaesthesia for any surgery is expected to increase, reflecting the rising prevalence of obesity.

Obesity is a disorder involving multiple organs, hence there are a number of implications concerning the anaesthesiologist. So a multidisciplinary approach is required for such patients. Obesity is accompanied by many complications in anaesthesia, including difficult airway. Obese patients who stand in need of general anaesthesia should have their airway protected as there is loss of patient's airway reflexes with the onset of induction of general anaesthesia. Hence, airway of obese population becomes a major arena to be mastered by an anaesthesiologist .[1,2]

Obesity is associated with anatomical and physiological difficult airway. In UK, the Fourth National Audit of the Royal College of Anaesthetists' and Difficult Airway Society showed that obese patients accounted for 42% of total individuals who experienced a major airway complication during anaesthesia (leading to death, brain damage, an emergency surgical airway or intensive care unit (ICU) admission)[6] . Any difficulty in tracheal intubation of such patients will lead to rise in morbidity and mortality associated with anaesthesia.

The implications of anatomic and physiologic changes on preoxygenation and securing definitive airway in obese patients is an important consideration in the perioperative period for an anaesthesiologist.

Table 2: Anatomical changes in obese patients and their implications in anaesthesia

Anatomical changes in obese patients	Anaesthetic implication on airway
Short and thick necks	Limited neck movement
Lower cervical and upper thoracic fat pads	Restriction of atlanto-axial joint movement and cervical spine mobility
Excessive fatty tissue fold in mouth, pharynx, neck	Airway lumen narrowing, difficult bag and mask ventilation
Posterior cervical, suprasternal, presternal fat and a very thick submental fat pad	Limited neck movement, difficult surgical airway
Large tongue	Restrict the movement of the laryngoscope, prone to develop obstructive sleep apnoea
Excess fatty tissue on chest/breasts, thorax, and abdomen	Reduced chest wall compliance, Decreased functional residual capacity

The above mentioned anatomical difficulties make it difficult to get the oral, pharyngeal and laryngeal axis in line for a successful endotracheal intubation. [3-5,14]

Physiologically, the increased body mass leads to increased metabolism of adipose tissue, further leading to increased oxygen consumption in body and increased carbon dioxide production. Thus these patients are susceptible to early hypoxia and raised CO2 levels if their ventilation is impaired. Due to increased body mass and heavy chest wall, there is reduced chest wall compliance (up to 30%). The reduction in compliance and increased work of breathing leads to additional stress response of the patient above surgical stress. On top

of increased work of breathing, the functional residual capacity (FRC) decreases with increase in BMI. Hence these patients are prone to hypoxia even while they are conscious and tend to desaturate rapidly once apnoeic as their oxygen reserve is reduced (reduced FRC), and oxygen consumption and demand increased, thus adequate pre-oxygenation and securing early definitive airway becomes a priority in such patients. [3-5]

Obesity is also known to increase the probability of many co-morbidities. These comorbidities further increase the possibility of perioperative morbidity and mortality. Adequate optimisation is required for such patients to improve morbidity and mortality in the preoperative period.

The gold standard technique to secure airway in any patient, especially obese patients, is endotracheal intubation. Direct laryngoscopy or endotracheal intubation is reported to be more difficult in the obese population in contrast to non-obese population. Juvin et al. conducted a study to compare endotracheal intubation difficulty in obese v/s lean patients. The study reported a 15.5% rate of difficult tracheal intubation in obese patients compared with a 2.2% rate in lean patients. They also observed that fall in saturation occurred more rapidly and more often in obese than in lean patients after induction of anaesthesia, despite a similar preoxygenation, owing to reduced FRC and reduced lung compliance in obese patients. [2]

As a solution to above complications, a substitute to endotracheal intubation, second generation supraglottic airway devices (SADs) or Laryngeal mask airways (LMA) have been introduced into practice. SADs are single-use or reusable devices that are placed in supraglottic area and can be used as a temporary method to secure airway during the administration of general anaesthesia or as a life-saving measure in a difficult airway or failed endotracheal intubation as outlined in the difficult airway algorithm. SADs are being used to oxygenate in difficult

bag and mask settings, to secure airway for short procedures and as a conduit for tracheal intubation. LMAs function as a safety device in “cannot ventilate, cannot intubate” situations. They have a potential benefit of securing airway with ease of insertion and fit over laryngeal tissues while ensuring least airway manipulation, hence minimal chances of haemodynamic instability occurring due to laryngoscopic response. SADs have now become a key in successful management of difficult airway. [2]

SADs have brought an outbreak in modern anaesthesia by revolutionising the practice of airway management. Murphy C et al in a review stated that the combination of anatomical difficulties like increased adipose tissue and physiological difficulties like decreased lung volumes in obese patients lead to challenging preoxygenation, difficult bag and mask ventilation and difficulty in securing definitive airway. They suggested that newer generation double lumen SADs can be used in obese population as they provide higher leak pressures. They can function as a guide for tracheal intubation. Although second generation SADs can be inserted safely in obese patients but there are increased risks of aspiration in such individuals. Hence SADs should be used cautiously in morbidly obese individuals.[14]

In obese patients, there is decrease in functional residual capacity and closing capacity. Hence, in these patients, the smaller airways close earlier as compared to normal patients, especially when anaesthetised. Thus obese patients are prone to desaturate early during laryngoscopy, before the definitive airway is secured. Kurien BB et al in a review stated that supraglottic airway devices (SADs) can be useful in scenarios of difficult laryngoscopy and intubation, like in morbidly obese patients. They stated that SADs can function as a saviour in difficult airway situation and can also be useful in obese patients undergoing short surgical procedures without the possibility of airway related complications. [5]

Zoremba M et al carried out a study on 162 patients undergoing short to medium duration surgeries in moderately obese patients to compare

the effects of intubation and Proseal LMA. They included the data of 134 patients after calculating the dropouts. The study aimed to evaluate the effect of airway manipulation on post-operative lung volumes and arterial oxygen saturation in early post-operative period. They also compared endotracheal intubation and Proseal LMA with respect to parameters like leak pressure, ease of intubation and urgency to secure airway. They concluded that lung function tests and oxygen saturation were significantly better in Proseal group. The study showed that LMA can be advantageous for moderately obese adults for early recovery of post-operative lung functions and can be useful in securing airway in obese patients in short surgeries. [20]

The worst-case scenario happens with a difficult airway in which both ventilation and intubation are difficult. This leads to multiple attempts at laryngoscopy, predisposing them to multiple episodes of rapid desaturation especially during laryngoscopy and endotracheal intubation. The above sequence of events lead to fluctuations in haemodynamic stress response and higher incidence of dysphonia, sore throat, hoarseness and dysphagia in post-operative period. [6-8] Seung HY et al conducted a randomised controlled trial to compare incidence of post-operative complications in intubation and LMA. They concluded that the use of LMA resulted in a statistically and clinically significant decrease in the incidence of laryngospasm during emergence, hoarseness of voice and coughing in post-operative period than while using an endotracheal tube. [21]

Cochrane systematic review compared studies that used Proseal LMA and endotracheal tube in obese patients. They came to the inference that although Proseal LMA takes longer time to secure airway, but once placed properly, it provides equivalent oxygenation and ventilation as endotracheal intubation. They also found significant reduction in post-operative complications such as coughing, sore throat, hoarseness, reduced post-operative desaturation episodes in

almost 75% of patients, improved oxygenation intra-operatively and post-operatively with the use of Proseal LMA. [6]

Despite various benefits offered by SADs, there are certain drawbacks of the same, including increased risk of gastric regurgitation and aspiration, incomplete insertion, inadequate ventilation, risk of laryngospasm and bronchospasm associated with SADs.[10] Second generation SADs are defined as **"those with special features that target to reduce the risk of aspiration"**, making these devices 'safer' than first generation ones. Reducing the risk of aspiration can be achieved by **venting of regurgitant material** via a **gastric channel.** Over a period of time, new modifications were done in classic LMA model to include second tube placement, lateral to the airway channel to facilitate passage of nasogastric tube, in order to create separate respiratory & oesophageal channels & permit easy escape of gastric contents to decrease chances of gastric insufflation. [12] The 4th National Audit Project of the Royal College of Anaesthetists and the Difficult Airway Society (NAP4) done in United Kingdom in 2011 reported many cases of aspiration with the use of first generation LMA in patients who had many risk factors for aspiration like obesity. The NAP4 project also popularised that second generation SADs were accompanied by lesser incidence of major airway complications. The project showed only 4% risk of aspiration can be associated with second generation SADs, as compared to 35% chances of aspiration observed with endotracheal intubation. They inferred that SAD can be an excellent choice for patients with difficult airway without fearing risk of aspiration. [5, 22]

Metus Oterkus et al conducted a research in 69 patients aged 18-60 years, who belonged to ASA grade I-II, undergoing septoplasty. They compared endotracheal intubation and Ambu AuraGain with respect to hemodynamic alterations and respiratory parameters and concluded that Ambu AuraGain was equivalent to ETT in terms of haemodynamic

instability and respiratory parameters and can function as an alternative to tracheal intubation.[23]

Lai CJ et al conducted a study in 40 ASA I-II patients who were undergoing laparoscopic pneumoperitoneum surgeries. They compared I-Gel with ETT in supine and trendelenburg position with respect to respiratory parameters. They found that I-Gel had significantly lower resistance and higher compliance as compared to ETT. They also found that there were no statistically significant differences in the leak fraction between the I-Gel and ETT groups. I-Gel produced similar leak volumes, leak fractions and airway pressures as in ETT. Moreover they found that the I-Gel group displayed no evidence of aspiration and the rate of post-operative sore throat was significantly less in the I-Gel group as compared to the ETT group. They concluded that I-Gel can be used as an alternative to ETT in surgeries that require laparoscopic pneumoperitoneum and trendelenberg position. [24]

Oropharyngeal leak pressure (OLP) is a measurable criteria that is used to access safety and compare efficacy of SADs. The performance of SADs can be measured by OLP. A higher OLP ensures there is better seal between the underlying mucosa and the SAD as compared to poor seal in lower OLP. Higher OLPs are preferred in obese patients, increased intra-abdominal pressure such as in laparoscopic surgeries and in patients with restrictive lung diseases.[13] OLP is reported to be affected by change in head and neck position of patient. This may concern patients undergoing surgery in head position other than the neutral. Kerai S et al conducted a study in 80 ASA I-II patients who underwent elective surgeries under GA, comparing oropharyngeal leak pressures in LMA protector and Proseal LMA. They concluded that the OLPs of LMA Protector and Proseal LMA are comparable in neutral, extension, flexion and rotation of head and neck positions. They also found that the OLP of both Proseal LMA and LMA Protector decrease significantly in head extension whereas OLP increases significantly with neck flexion and rotation. [25]

OLP can also be used to determine the accuracy of LMA placement in supraglottic area. Higher OLPs indicate the likelihood of successful supraglottic device placement. Kim GW et al reported a study of 100 patients comparing the efficacy of laryngoscope-guided LMA insertion with blind LMA insertion using OLP as an indicator to determine the adequacy of LMA placement. They found that OLP was significantly lower in the blind insertion group whereas higher leak pressures with better seal were found in the laryngoscope-guided insertion group. The ease of insertion was not statistically significantly different between the two groups. The time taken for insertion of LMA was significantly longer in blind insertion group. They inferred that laryngoscopy guided technique may be a useful technique for LMA insertion and can provide better seal pressures as compared to traditional blind technique. [26]

There are many methods to assess and measure OLP. In a study by Keller C et al conducted in 80 patients, four methods were compared to check airway sealing pressure of LMA in adults. Test 1 is Audible noise: listening to audible noise over the mouth to note presence of any audible leak. Test 2 is Oral capnography: placement of a 5 cm carbon dioxide (EtCO2) sampling line inside the mouth along with the LMA and noting when the EtCO2 was first seen above baseline on the monitor screen. Test 3 is Manometric stability: observing aneroid manometer dial as the pressure from the breathing system is increased and noting the airway pressure at which the dial reached stability i.e. the airway pressures on monitor at which the leak observed and the fresh gas flow were in equilibrium. Test 4 is Auscultation: detection of an audible noise or leak by placing a stethoscope lateral to the thyroid cartilage. They observed that all the tests were good for clinical purposes but manometric stability test provided higher mean values and inter-observer reliability making it better for research purposes.[27]

Newer supraglottic airway devices are designed to achieve higher OLPs. Various such models are : LMA Proseal, LMA supreme,

AuraGain, I-Gel etc. [14] In this study, we aimed to study two SADs, namely, I-Gel and Ambu AuraGain.

“I-gel “ (Intersurgical Ltd, Wokingham, Berkshire) developed in 2007 [6,8], having a soft gel like cuff made of thermoplastic elastomer (styrene ethylene butadyiene styrene), which is transparent, soft, gel like & designed to optimally fit over the hypolaryngeal and perilaryngeal structures, without any inflatable cuff. [15,16] Ambu AuraGain (Ambu, Ballerup, Denmark) is a second generation novel cuffed SGA introduced in 2015, made of polyvinyl chloride (PVC), which has a preformed curve, bite block & also a built in gastric port. [4]

Wong DT et al conducted a randomized controlled trial to compare the OLP of the AuraGain with LMA Supreme in adult patients undergoing surgery under general anaesthesia. They observed that the mean OLP was significantly higher in the AuraGain group than in the Supreme group. They also observed that AuraGain group took significantly longer time to insert as compared to the Supreme group with better ease of insertion in the Supreme group. There were no statistically significant differences in the post-operative complications in the two groups. They concluded that since AuraGain group attained higher OLP, AuraGain can become a better option in wide range of patients and surgeries especially with positive pressure ventilation as it will help in increasing the margin of safety to prevent risk of aspiration. [28]

Meenakshi Sumadevi Pradeep et al conducted a randomised controlled study in 90 ASA I-II patients who underwent laparoscopic surgeries under general anaesthesia, comparing Ambu AuraGain, I-gel and Supreme LMA. They studied the three groups with respect to insertion time, ease of insertion, attempts required for insertion and Oropharyngeal leak pressure. They observed that time taken for insertion of LMA was significantly higher in Ambu AuraGain, requiring maximum number of attempts amongst the three groups but the ease of its insertion was maximum. All the three groups had comparable

haemodynamics and post-operative outcome. Ambu AuraGain had significantly higher oropharyngeal seal and higher leak pressures. Thus they concluded that Ambu AuraGain can be a better alternative than other two devices for patients undergoing laparoscopic surgeries under general anaesthesia. [11]

Kim HJ et al conducted a research to compare AuraGain and I-gel on 68 pediatric patients from 6 months to 6 years of age, weighing 5–20 kg, undergoing extremity surgeries under general anaesthesia. They observed that I-gel group required more additional airway manipulations during the insertion of the device and maintenance of ventilation as compared to AuraGain group. Also fiberoptic view was found to be better with AuraGain group. However they found that OLP was significantly higher with I-gel group. Thus they concluded that AuraGain is a better option requiring less airway manipulations but I-gel would be more beneficial in surgeries where higher OLP is required.[29]

Singh K et al conducted a prospective randomised study between Ambu AuraGain and Proseal LMA in 60 patients who underwent laparoscopic cholecystectomy under general anaesthesia. They compared the two groups and evaluated them with respect to OLP, number of insertion attempts, ease of insertion, time required for placement and pharyngeal mucosal pressures in the two groups. They found no statistically significant difference in OLP, ease of insertion and first attempt success rate between the two groups. The insertion time of Ambu AuraGain was longer than that of Proseal LMA with low pharyngeal mucosal pressures in AuraGain group. Thus they concluded that Ambu AuraGain provides adequate sealing pressures and ventilation and can be used in laparoscopic surgeries allowing lower pharyngeal mucosal pressures.[30]

Prabha R et al conducted a study to compare I-Gel in obese and non-obese patients who underwent surgery under general anaesthesia. A total of 32 patients were studied and they found that OLP was higher in obese patients group in contrast to non-obese group but was not statistically significant. They postulated that excess perilaryngeal tissue

in obese patients may lead to better supraglottic seal between the cuff of I-Gel and laryngeal mucosa. They concluded that in obese as well as non-obese patients, I-Gel can be equally effective when used to secure airway for surgeries under general anaesthesia. [31]

Mihara T et al conducted a study to compare AuraGain and I-gel in 100 paediatric patients upto 12 years of age, weighing 5–30 kg, undergoing elective surgery with an expected surgery time of less than 2 hours under general anaesthesia. They found that OLP was higher for the I-Gel group than that of AuraGain group. The first-attempt success rate was comparable between the two devices. They concluded that I-Gel took less time for successful placement, had higher OLP and lower incidence of blood staining than AuraGain. [32]

Uppal V et al conducted a study in 20 patients during positive controlled ventilation to compare cuffed endotracheal tube with I-Gel measuring respiratory parameters. They observed that the two groups were comparable with respect to leak fractions at 15-20 cm H2O. There was no case that documented gastric insufflations with I-gel at any pressure. It was concluded that I-gel can be used as a suitable alternative to tracheal intubation during positive control ventilation. [33]

Solanki et al conducted a study to compare ideal and actual body weight for selecting optimal size of Proseal LMA in 124 overweight and obese patients. They found that the smaller size cuff which was chosen according to ideal body weight provides better sealing and less trauma than the larger size cuff chosen according to actual body weight due to the existence of smaller upper airway in obese patients and inferred that ideal body weight is better criteria for LMA size selection when compared to actual body weight in overweight and obese. [34]

Theiler et al conducted a study in children scheduled for elective day care surgery under general anaesthesia to compare paediatric sized I-Gel with Ambu Auraonce with respect to OLP, first attempt overall success, time to sufficient ventilation and adverse events. They concluded that I-Gel showed significantly higher leak pressures than

Ambu Auraonce and can be used in surgeries that require higher leak pressures. There were no major side effects in any of the groups. [35]

Sabuncu U et al conducted a study in 114 ASA I-II patients who underwent laparoscopic surgeries under general anaesthesia to compare Ambu AuraGain and I-Gel with endotracheal intubation for securing airway with respect ease of insertion and perioperative complications. They found that hemodynamic instability is lesser seen in Ambu AuraGain group and they concluded that Ambu AuraGain can be a better option than endotracheal intubation in patients where haemodynamic instability has to be avoided.[36]

Dwivedi P et al conducted a study in 45 paediatric patients from 1-12 years of age who underwent elective non-ocular surgeries under general anaesthesia to compare endotracheal tube, Ambu AuraGain and I-gel with respect to measurement of intraocular pressure (IOP) changes of both eyes at pre-defined intervals. They found that endotracheal intubation caused significant increase in IOP as compared to Ambu AuraGain and I-gel. Thus they concluded that Ambu AuraGain and I-gel are better than endotracheal tube in the paediatric patients to avoid increase in intraocular pressures.[37]

Chatterjee R et al conducted a study in 88 patients from 1-5 years, weighing 10-30 kg, undergoing elective inguinal and urology procedures under general anaesthesia. They found that I-Gel demonstrated significantly higher leak pressures in paediatric population as compared to Ambu AuraGain, while Ambu AuraGain took less time to insert than I-Gel but the insertion time of both groups was comparable. They concluded that I-Gel provided better leak pressures, hence less chances of aspiration, whereas Ambu AuraGain showed better clinical performance in terms of ease of insertion. [38]

Lee JH et al conducted a study to compare AuraGain and I-gel on 93 pediatric patients from 1 month to 7 years of age, who underwent elective surgeries under general anaesthesia. They observed that OLP noted immediately after insertion and after 10 minutes of insertion was statistically non-significant in I-gel group and AuraGain group. They also found that I-Gel required more additional airway manipulations

during the insertion of the device as compared to AuraGain group. Also fiberoptic view was found to be better in AuraGain group. They found that the rate of complications was higher with I-Gel group. Thus they concluded that I-Gel and AuraGain are comparable in terms of OLP, but AuraGain can be a better option in paediatric patients considering other factors.[39]

After thorough search of the available literature, we planned to further compare I-Gel and Ambu AuraGain with respect to oropharyngeal leak pressures, time of insertion, ease of insertion, haemodynamic stability and respiratory parameters in obese patients in laparoscopic surgeries.

MATERIALS AND METHODS

SOURCE OF DATA

The study was conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana, after approval from the Institutional Ethics Committee. A written informed consent was obtained from all patients selected for study.

METHOD OF COLLECTION OF DATA

A prospective, randomised, interventional study was conducted on ASA II and III adults undergoing Laparoscopic surgeries. A total of 50 patients were recruited for the study and an equal number were randomised using computer generated random numbers contained in sealed, sequentially numbered envelopes, which were opened by an independent anaesthesiologist.

Inclusion Criteria

- Age 18 -70 years
- BMI > 30 kg/m²
- Fulfilling the criteria of ASA II & III

Exclusion Criteria

- Laparoscopic converted to open surgery
- Infections or Pathology of airway.
- Limited mouth opening (<24 mm)
- Patients with history of hiatus hernia
- Pregnancy, reduced lung compliance
- Edentulous
- Need for conversion from LMA to ETT
- Refusal to participate

Group Allocation-

A written informed consent was obtained from all the patients. Patients were randomly divided into 2 groups of 25 patients each. Randomisation was done by computer generated random numbers contained in sealed, sequentially numbered envelopes, which were opened by an independent anaesthesiologist.

Group (I)- I-Gel LMA of appropriate size was inserted by the conventional technique with concavity facing mandible in a pen holding manner and inserting the device till it fits over the larynx (Brain's Technique).[40,41]

Group (A)- Ambu AuraGain LMA of appropriate size was inserted by the standard recommended insertion technique. [42]

All patients were subjected to routine pre-operative assessment and standard fasting protocols.

An appropriate size of LMA was selected for the respective group, according to the weight of the patient. The size of LMA in group (I) was selected based on patient's weight as per manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5). [31,43] The size of LMA in group (A) was based on patient's weight as per the manufacturer's guidelines (30-50 kg - size 3, 50-70 kg - size 4, >70 kg - size 5).[19,28]

In the operating room (OR), all patients were positioned in Ramp position. Monitors were attached in the form of pulse oximeter, non-invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$), 5 lead electrocardiography (ECG). After positioning of patient on OR table, baseline values were recorded from the mean of three values. Intravenous access was secured and intravenous injections of midazolam 0.05 mg/kg and metoclopramide 10 mg or ondansetron 4 mg were administered. After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical

face mask, anaesthesia was induced with intravenous injection of fentanyl 2mcg/kg and 1% propofol 2-2.5 mg/kg titrated till loss of verbal response. Neuromuscular blockade was achieved by intravenous injection of atracurium 0.5 mg/kg.

The selected LMA was fully lubricated with water soluble jelly prior to insertion. For group (A), Ambu AuraGain LMA was fully deflated. After achieving adequate depth of anaesthesia and muscle relaxation, the insertion of randomly selected LMA(I-Gel/ Ambu AuraGain) was performed by a single anaesthesiologist with >3 years of experience in using the SAD devices. The standard recommended insertion technique was tried for the first attempt. In case of resistance, adjusting maneuvers such as lateral rotation of cuff, jaw lift, head and neck extension will be applied and noted.[11] An independent observer noted the time of insertion of LMA [44]. After insertion, the cuff of Ambu AuraGain was inflated with air to attain a cuff pressure of 60 cm of water as measured by hand held cuff pressure manometer.

A nasogastric tube of appropriate size was passed through the gastric tube channel in all the cases. The lungs were mechanically ventilated using volume controlled ventilation delivered by an anaesthesia work station (Drager Fabius Plus/Primus) to deliver a tidal volume of 8ml/kg, respiratory rate to maintain $EtCO_2$ between 30 and 40 mmHg, inspiratory and expiratory ratio of 1:2 and a peak end-expiratory pressure of 5 cm of water.

Initial assessment of ventilation was performed by observing the square wave capnograph and chest rise.

The total fresh gas flow was maintained at 1.5 L/min. Anaesthesia was maintained by desflurane or sevoflurane in 50:50 oxygen and nitrous oxide or air. Additional fentanyl 1mcg/kg i.v. was given when clinically needed during anaesthesia. Oropharyngeal pressures were measured before and after achieving pneumoperitonium. Any need for conversion

for LMA to ETT was considered as failure of study and the case was considered as a dropout from study.

At the end of the procedure neuromuscular blockade was reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.005 mg/kg and LMA was removed after confirming the return of spontaneous and normal pattern of ventilation with sustained head lift for atleast 5 seconds. Patients were then shifted to post anaesthesia care unit for observation.[31]

Observations:

PRIMARY OUTCOME-

To compare oropharyngeal leak pressures of I-Gel and Ambu AuraGain- To perform the OLP, the fresh gas flow was adjusted to 3L/min, and the adjustable pressure limiting valve of the circle system was completely closed. With no peak end expiratory pressure the minimum airway pressure was measured at which audible gas leak started to occur as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures were not allowed to exceed 40 cmH_2O. [43]

Successful placement at first attempt **-** The LMA was deemed to be correctly placed if there was “successful ventilation”, which was confirmed by: Bilateral symmetrical chest wall rise, auscultation of breathe sounds, square wave capnographic curves and no oropharyngeal leak.

SECONDARY OUTCOMES-

1. **Time of insertion-**The insertion time was defined as the time from picking up the device until confirmation of successful ventilation. Maximum time allowed for each attempt was 60 seconds.

2. **Number of attempts of insertion of device and failed attempt**

- An attempt was defined as the insertion of LMA between teeth until LMA was assumed to be correctly placed & cuff (in Ambu AuraGain) properly inflated till EtCO2 is seen on monitor.
- A maximum of 3 attempts were allowed.
- Any change in size of device was also considered as an attempt.
- If after three attempts of LMA placement, the criteria for successful placement of LMA was not met with, it was considered as failed placement. Need for the change of type of airway device was considered as failed placement.

3. **Ease of insertion -** The Ease of insertion was graded by the anaesthesiologist inserting the device as easy = 1, moderate = 2, difficult = 3 and impossible = 4.

4. Number of attempts of gastric tube placement- The gastric tube was passed through the gastric port of the device and correct position was confirmed by inflation of air & epigastric auscultation or aspiration of gastric contents.

5. Manipulations done during insertion - Any manipulations done during insertion of the LMA was noted down like gentle withdrawal with advancement of the LMA, lateral rotation of LMA, chin lift, jaw thrust, head extension and neck flexion.

6. Haemodynamic parameters – Heart rate (HR), Non invasive BP (NIBP), Saturation (SpO_2) were recorded at 0/1/5/10/15/30 minutes starting from induction.

7. Respiratory Parameters – Expired Tidal Volume, Peak Pressure, Plateau Pressure and EtCO2 were recorded at 0/1/5/10/15/30 minutes starting from induction.

8. Complications- At the time of removal of LMA, any staining of the LMA with blood was noted. Number of episodes of desaturation i.e. SpO_2< 90% were noted down, the patients were mask ventilated with 100% oxygen till optimal SpO_2 level was reached (95%).

Patients were followed up for 12 hours after the surgery for complaints of sore throat, dysphagia and dysphonia. Sore throat was rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up in post anaesthesia care unit. A score of more than 4 on NRS will be considered as sore throat.

STATISTICAL ANALYSIS-

Data was described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups were done using ANOVA or Kruskal-Wallis Test with post hoc Tukey's. For comparing categorical data, Chi square ($\chi 2$) test was performed. A probability value (p value) less than 0.05 was considered statistically significant. All statistical calculations were done using (Statistical Package for the Social Science) SPSS 21 version (SPSS Inc., Chicago, IL, USA) statistical program for Microsoft Windows.

Sample size calculation-

The objective of the study was to compare oropharyngeal leak pressures in I-Gel and AuraGain in laparoscopic surgeries in obese patients. The formula used is as under:

The formula used is as under:

$n = (\sigma 12 + \sigma 22) (Z\alpha + Z\beta)^2/(m1 – m2)^2$

Where,

Zα = Value of standard normal variate corresponding to α level of significance (1.96)

Zβ = The standard normal deviate for desired power (2.326)

m = Average

σ = Standard deviation

Assumptions:

From the study conducted by Meenakshi Sumadevi Pradeep et al [11]

Mean Group (m1) = 25.17

Mean Group (m2) = 29.63

Coefficient of variation = 150%

Standard deviation Group (σ1) = 3.24

Standard deviation (σ2) = 3.56

With the above assumptions the sample size for 95% confidence level & 99% power worked out 21 in each group. This number had been increased to 25 per group **(a total of 50)** to allow for a predicted dropout from treatment.

OBSERVATIONS AND RESULTS

CONSORT Flow Diagram for the study

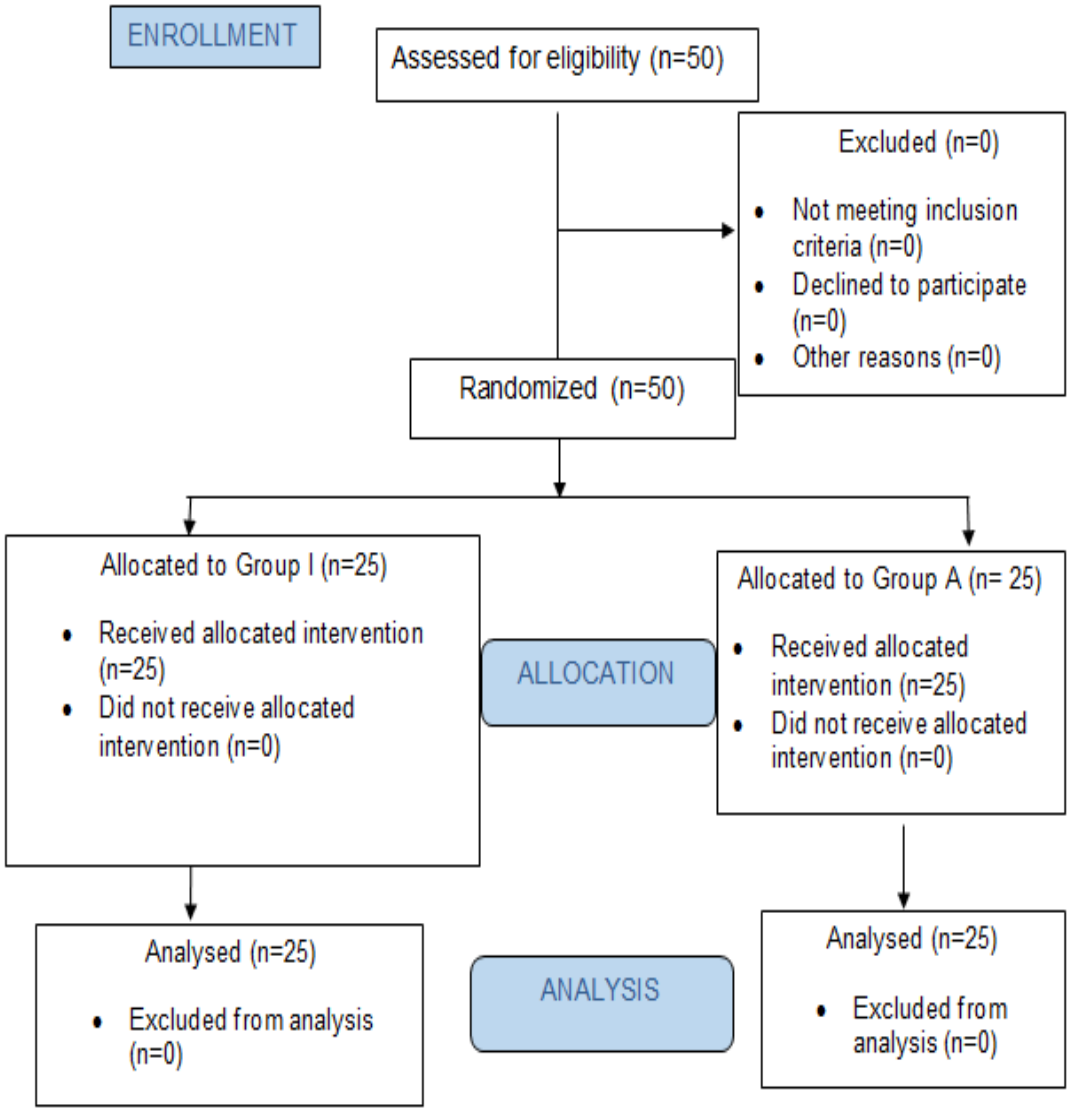


Figure 1: Consort flow diagram of the study

This randomised study was conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital on a total of 50 obese patients belonging to ASA II and III physical status posted for elective laparoscopic surgeries. They were randomly allocated by computer generated numbers in 2 groups of 25 patients each.

In Group I, I-Gel LMA was used to secure airway.

In Group A, Ambu AuraGain LMA was used to secure airway.

DEMOGRAPHIC PROFILE

Table 3: Distribution of patients according to gender

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Gender	F	9	36.0%	13	52.0%	22	1.299	0.254
	M	16	64.0%	12	48.0%	28		
Total		25	100.0%	25	100.0%	50		

In Group I, there were 64% males and 36% females whereas in Group A there were 48% males and 52% females. The groups were statistically non significant with respect to gender.

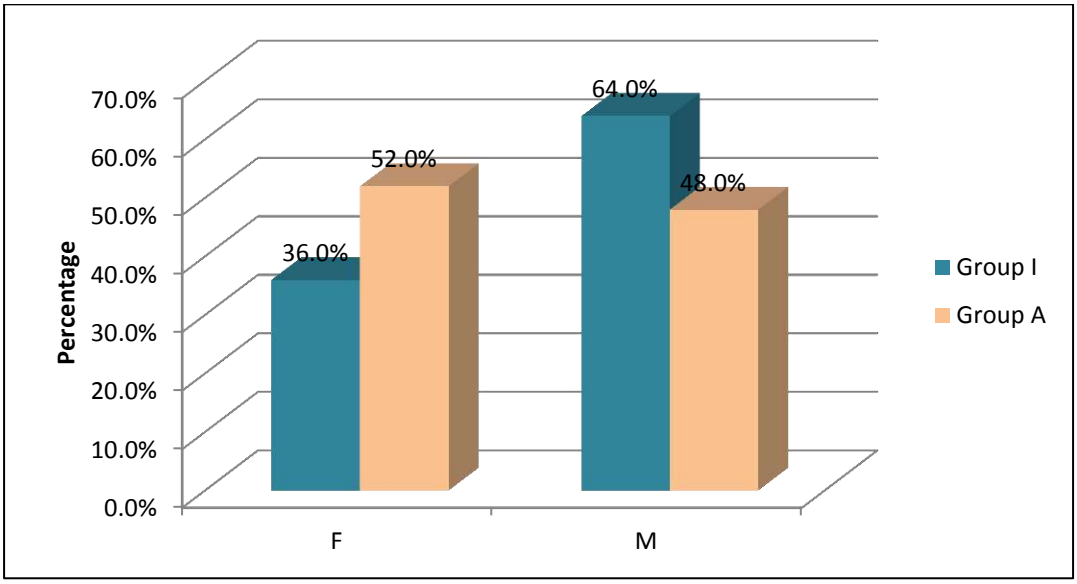


Figure 2: Distribution of patients according to gender

Table 4 : Distribution of patients according to age (years)

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
Age(years)	47.88	12.10	50.96	15.78	-0.774	0.442

Both the groups were comparable with respect to age. Mean age of Group I was 47.88 ± 12.10 years and that of Group A was 50.96 ± 15.78 years, with p-value being non significant.

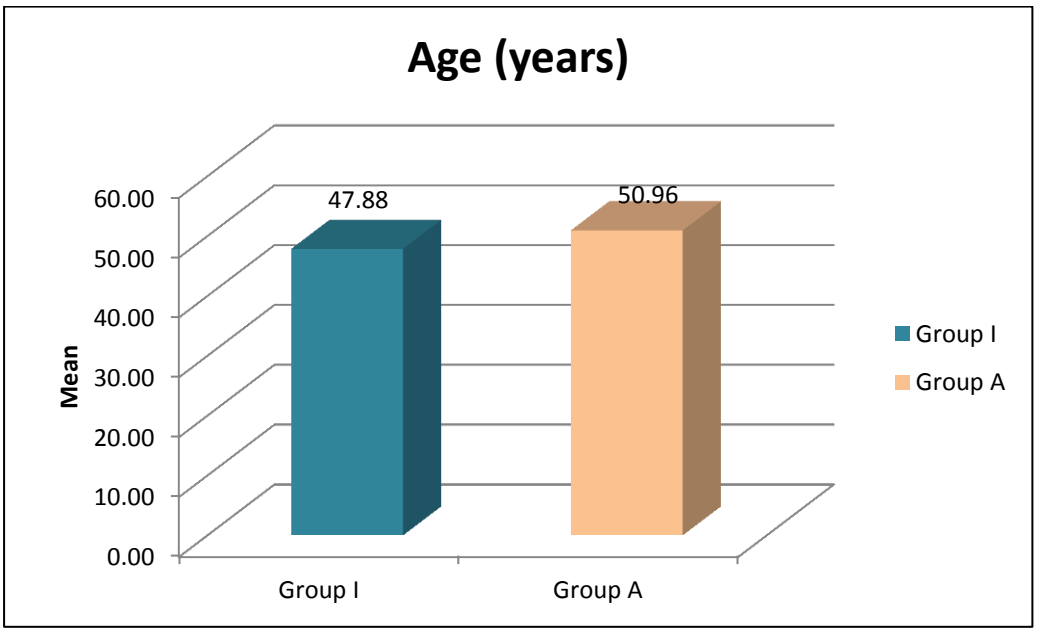


Figure 3 : Distribution of patients according to age (years)

Table 5 : Distribution of patients according to height (cm), weight(kg) , BMI (kg/m^2) and neck circumference

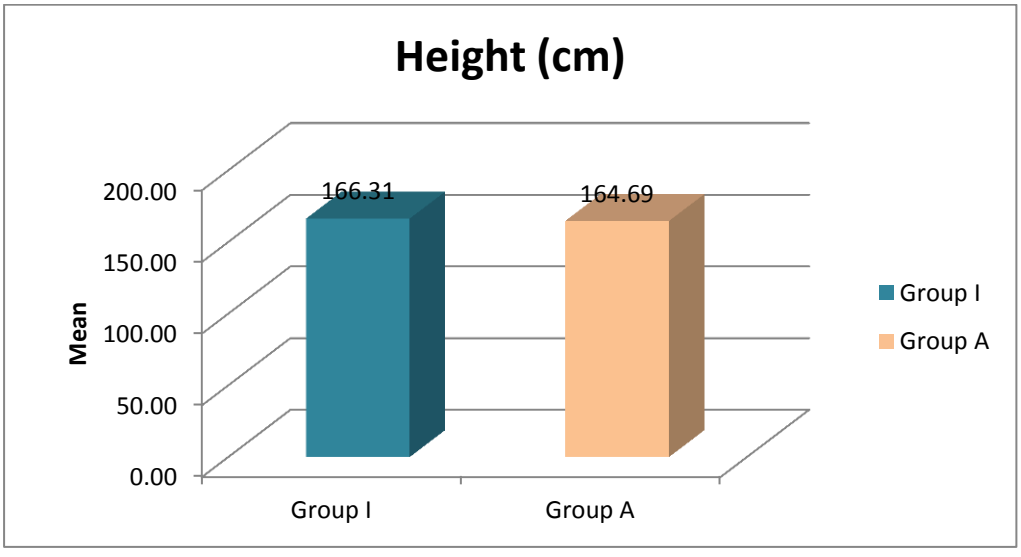
	Group I		Group A		t/Z	p-value
	Mean	SD	Mean	SD		
Height (m)	166.31	8.02	164.69	8.32	0.700	0.487
Weight (kg)	92.76	15.64	90.24	15.92	0.565	0.575
BMI(kg/m^2)	33.60	4.00	33.16	3.90	0.401	0.690
Neck circumference (cm)	39.42	1.26	39.16	1.37	-1.109	0.268

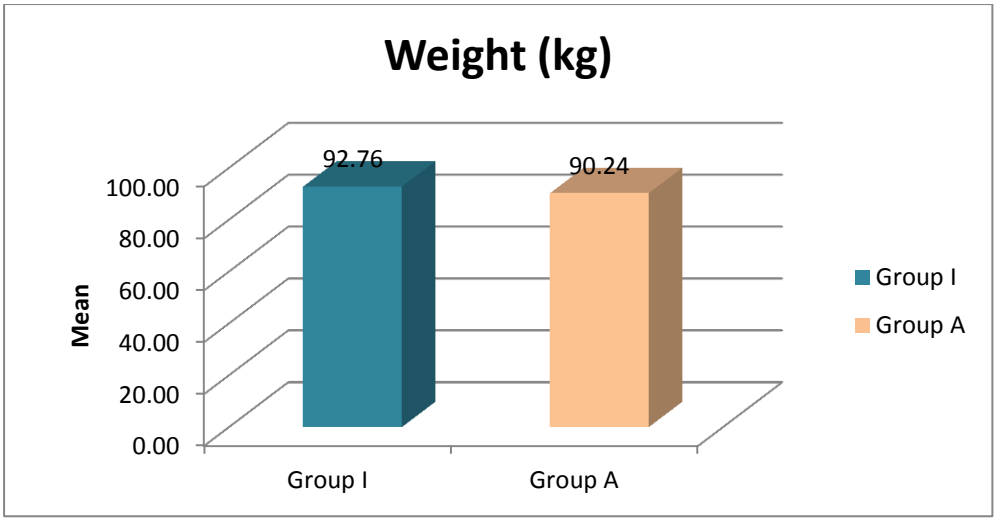
Both the groups were comparable with respect to height (cm), weight (kg) and BMI (kg/m²) and neck circumference (cm). The mean height of Group I was 166.31 ± 8.02 cm and of Group A was 164.69 ± 8.32 cm.

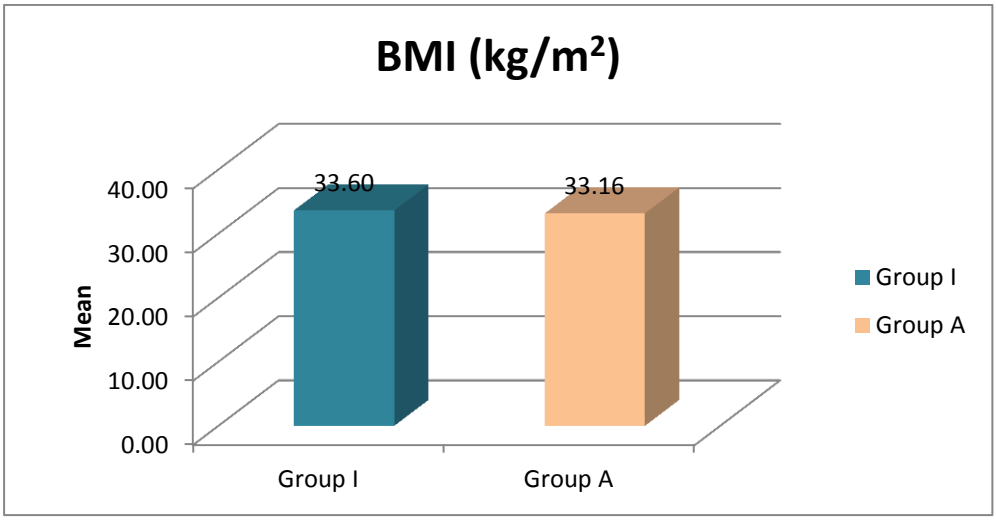
The mean weight of Group I was 92.76 ± 15.64 kg and Group A was 90.24 ± 15.92 kg.

Mean BMI of Group I was 33.60 ± 4.00 kg/m² and in Group B was 33.16 ± 3.90 kg/m².

The mean neck circumference of Group I was 39.42 ± 1.26 cm and of Group A was 39.16 ± 1.37 cm.







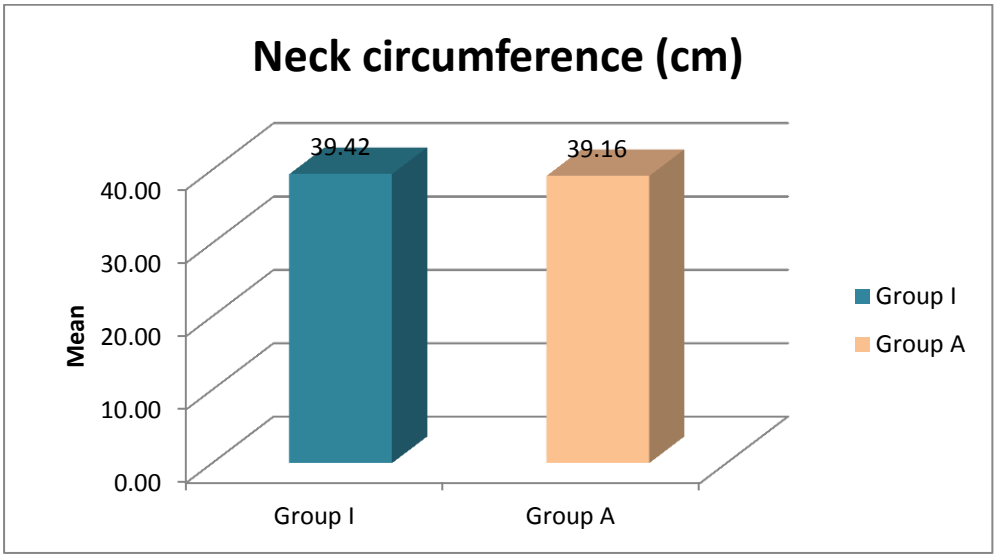


Figure 4: Distribution of patients according to height (cm), weight (kg) and BMI (kg/m^2) and neck circumference (cm)

Table 6 : Distribution of patients according to ASA grading

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
ASA	II	19	76.0%	17	68.0%	36	0.397	0.529
	III	6	24.0%	8	32.0%	14		
Total		25	100.0%	25	100.0%	50		

The two groups were comparable in terms of ASA grading. 76% of patients of group I and 68% of group A belong to ASA II. 24% of patients of group I and 32% of group A belong to ASA III.

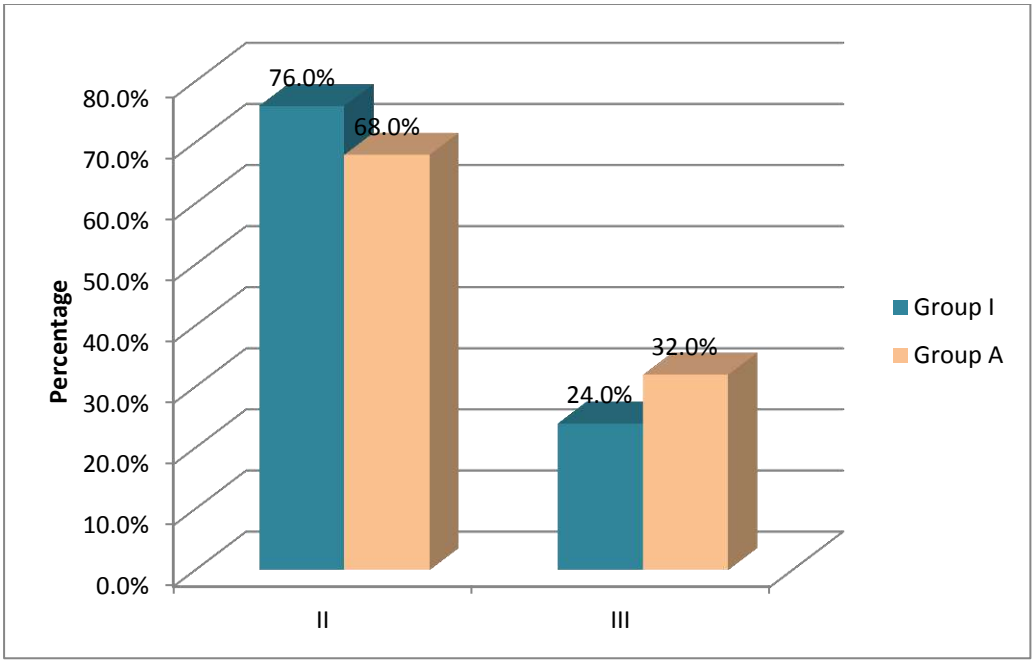


Figure 5 : Distribution of patients according to ASA grading

Table 7 : Distribution of patients according to mean duration of surgery

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
Duration of surgery (min)	108.00	23.32	107.40	28.62	-0.311	0.756

The two groups were comparable in terms of duration of surgery with mean duration of surgery for group I being 108 ± 23.32 minutes and Group A being 107 ± 28.62 minutes

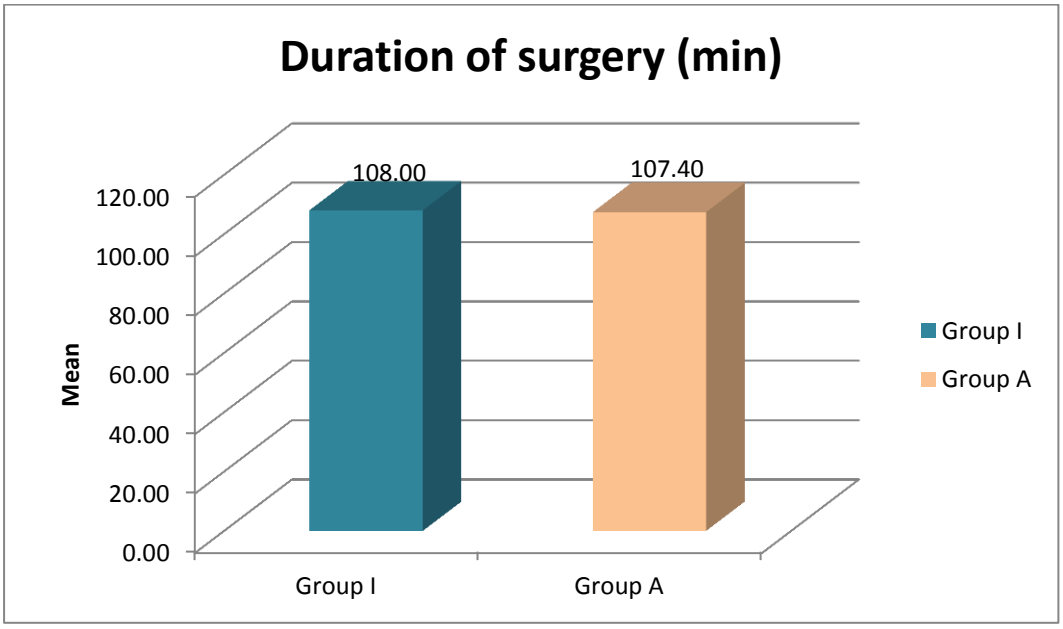


Figure 6 : Distribution of patients according to mean duration of surgery

Table 8: Distribution of patients according to size of LMA inserted

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Size of LMA	3	1	4.0%	1	4.0%	2	0.083	0.959
	4	11	44.0%	12	48.0%	23		
	5	13	52.0%	12	48.0%	25		
Total		25	100.0%	25	100.0%	50		

The size of LMAs used in both groups was comparable. In Group I, the size of I-Gel used were 3, 4 and 5 in 4%, 44% and 52% respectively. The sizes used in Group A were 3, 4 and 5 in 4%, 48% and 48% respectively. Most commonly used size of LMA in group I was size 5. In Group A, the most commonly used size of LMA were 4 and 5.

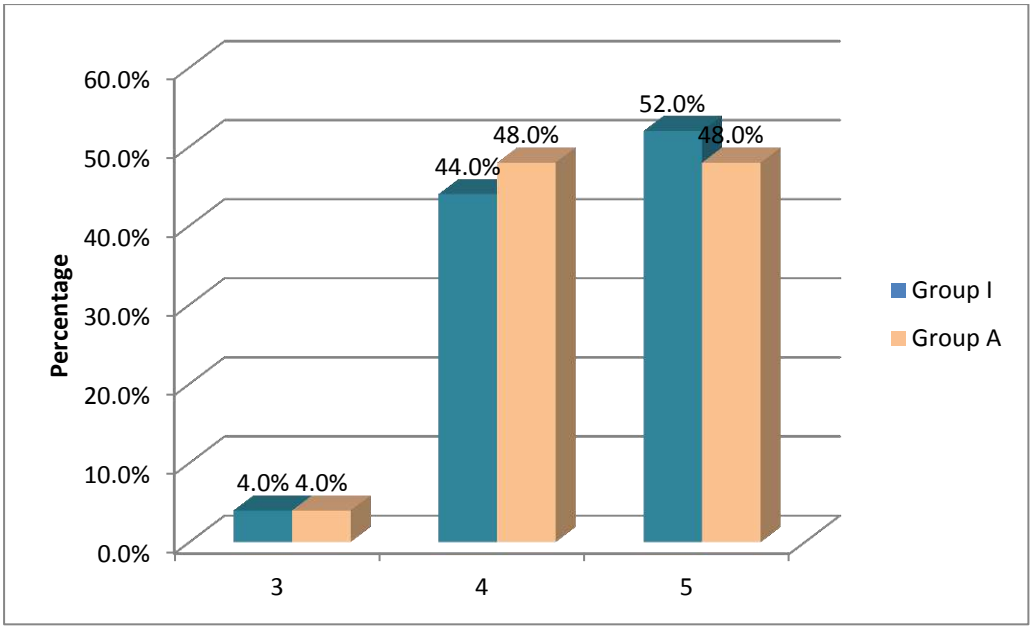


Figure 7: Distribution of patients according to size of LMA inserted

Table 9: Distribution of patients according to mean of size of LMA inserted

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
Size of LMA	4.48	0.59	4.44	0.58	-0.264	0.792

The mean of size of LMAs used in both groups were comparable. In Group I, the mean size of I-Gel used was 4.48 ± 0.59. In Group A, the mean size of Ambu AuraGain used was 4.44 ± 0.58.

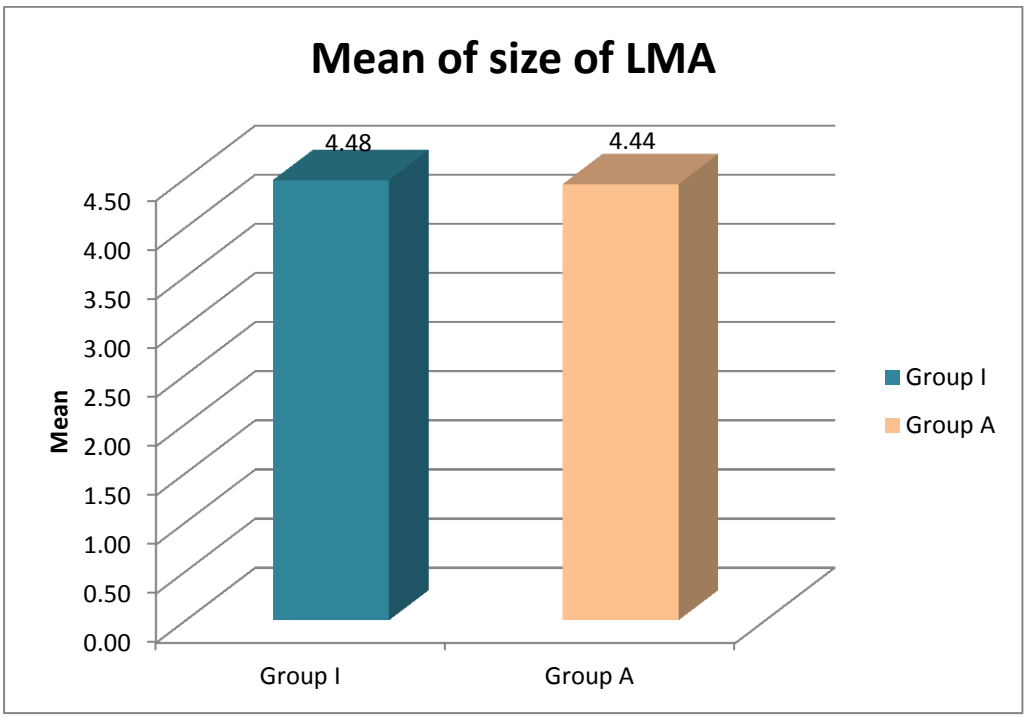


Figure 8: Distribution of patients according to mean of size of LMA inserted

Table 10 : Distribution of patients according to Mallampati score (MPS)

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
MPS	I	0	0.0%	1	4.0%	1	1.287	0.732
	II	9	36.0%	7	28.0%	16		
	III	13	52.0%	14	56.0%	27		
	IV	3	12.0%	3	12.0%	6		
Total		25	100.0%	25	100.0%	50		

The two groups were comparable in terms of Mallampati score (MPS) grading of the patients. In Group I, the MPS of patients were II, III and IV in 36%, 52% and 12% respectively. In Group A, the MPS of patients were I, II, III and IV in 4%, 28%, 56% and 12% respectively. Most common MPS of patients in group I and in Group A was III .

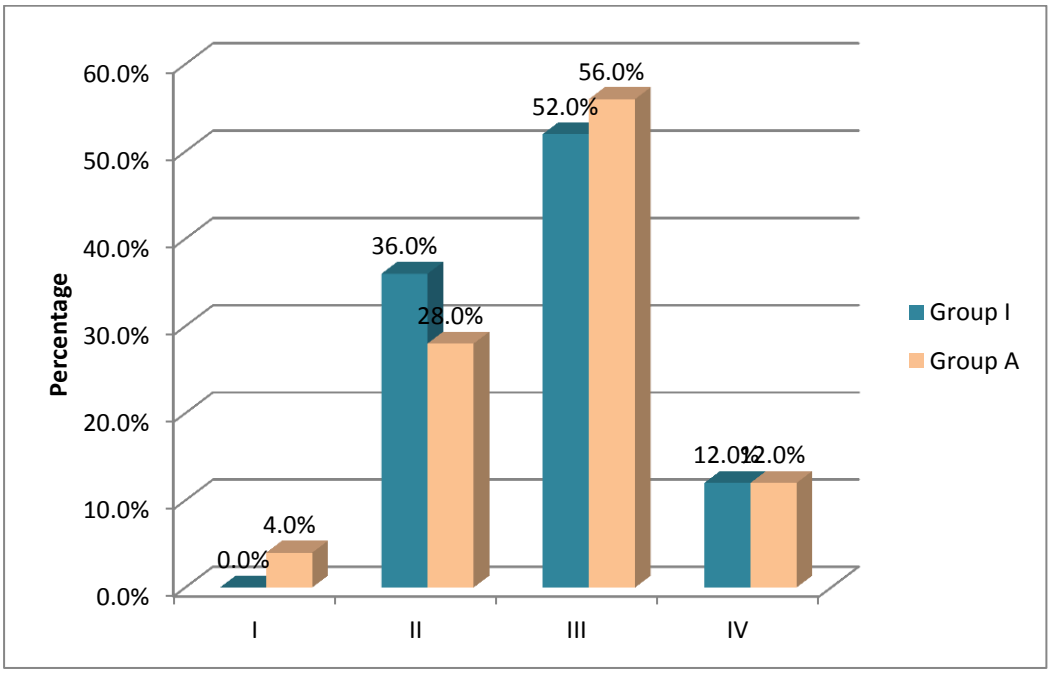


Figure 9: Distribution of patients according to Mallampati score (MPS)

Table 11: Distribution of patients according to thyromental distance

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Thyromental distance (cm)	> 6.5 cm	20	80.0%	20	80.0%	40	0.001	1.000
	< 6.5 cm	4	16.0%	4	16.0%	8		
	6.5 cm	1	4.0%	1	4.0%	2		
Total		25	100.0%	25	100.0%	50		

The two groups were comparable in terms of thyromental distance of the patients. In Group I, the thyromental distance of patients were > 6.5 cm, 6.5 cm and < 6.5 cm in 80%, 4% and 16% respectively. Similarly in Group I, the thyromental distance of patients were > 6.5 cm, 6.5 cm and < 6.5 cm in 80%, 4% and 16% respectively. The most common thyromental distance in both groups was > 6.5 cm.

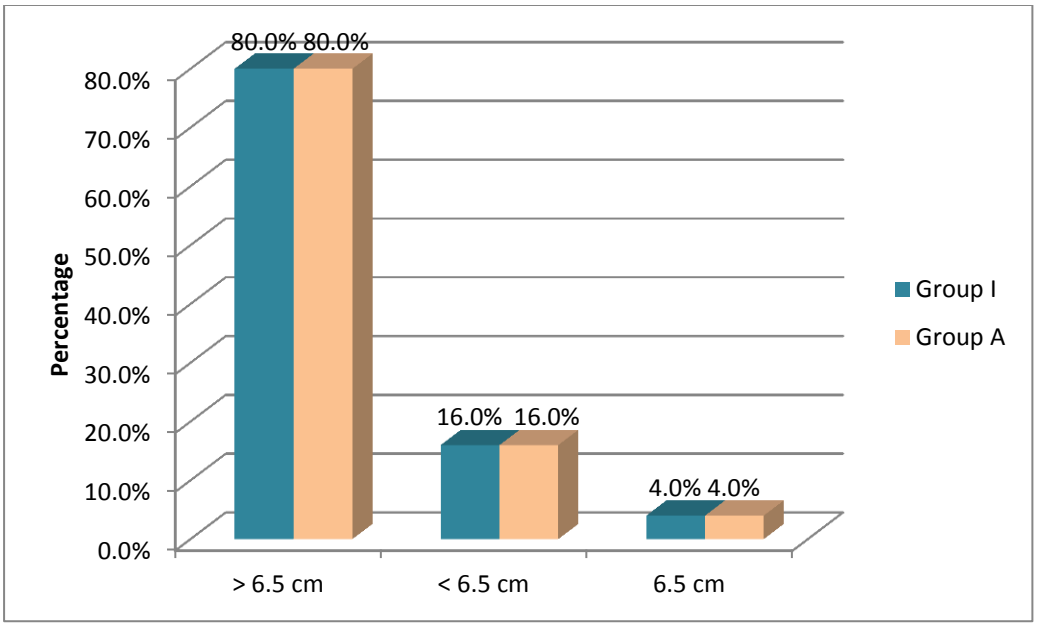


Figure 10 : Distribution of patients according to thyromental distance

Table 12 : Distribution of patients according to mouth opening

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Mouth opening	> 3 FB	25	100.0%	24	96.0%	49	1.02	0.312
	2- 3 FB	0	0.0%	1	4.0%	1		
Total		25	100.0%	25	100.0%	50		

The two groups were comparable in terms of mouth opening of the patients. In Group I, the mouth opening of patients were > 3 Finger Breadth (FB) in 100% of the patients, whereas in Group A, the mouth opening of patients were > 3 FB in 96% of the patients.

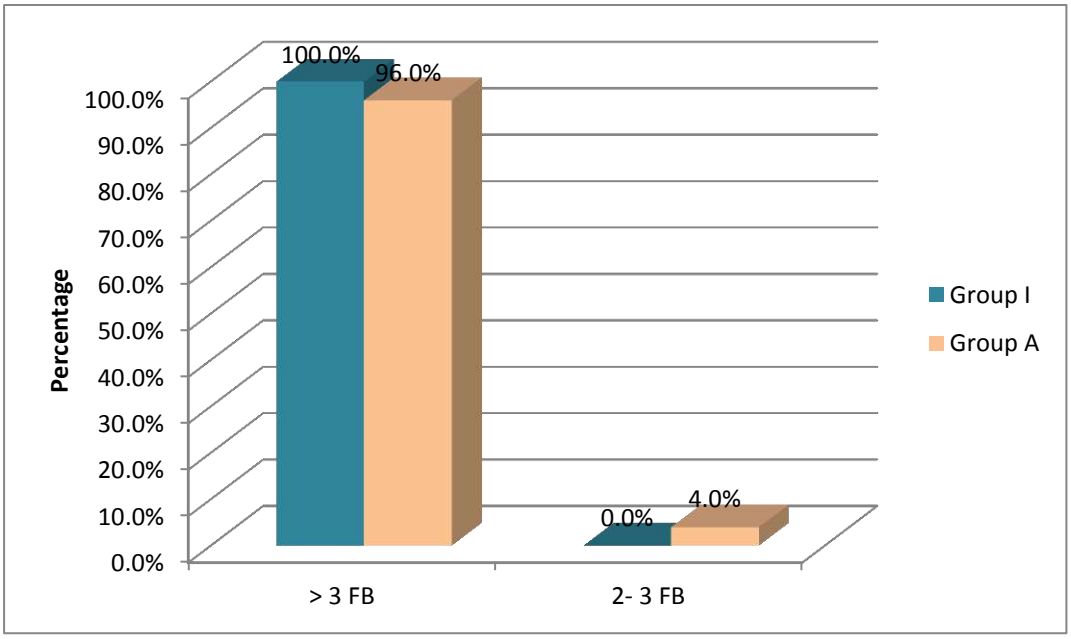


Figure 11 : Distribution of patients according to mouth opening

Table 13 : Distribution of patients according to Co-morbidities

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
DM	NO	23	92.0%	20	80.0%	43	1.495	0.221
	YES	2	8.0%	5	20.0%	7		
HTN	NO	16	64.0%	13	52.0%	29	0.739	0.390
	YES	9	36.0%	12	48.0%	21		
COPD	NO	25	100.0%	25	100.0%	50		
OSA	NO	25	100.0%	24	96.0%	49	1.02	0.312
	YES	0	0.0%	1	4.0%	1		
Total		25	100.0%	25	100.0%	50		

Diabetes mellitus was present in 8% of patients in Group I and 20% of patients in Group A. Similarly hypertension was present in 36% of patients in Group I and 48% of patients in Group A. No patient in both groups was known to have Chronic obstructive pulmonary disease. No patient in Group I had Obstructive sleep apnoea (OSA) and 4% of patients in Group A were known to have OSA

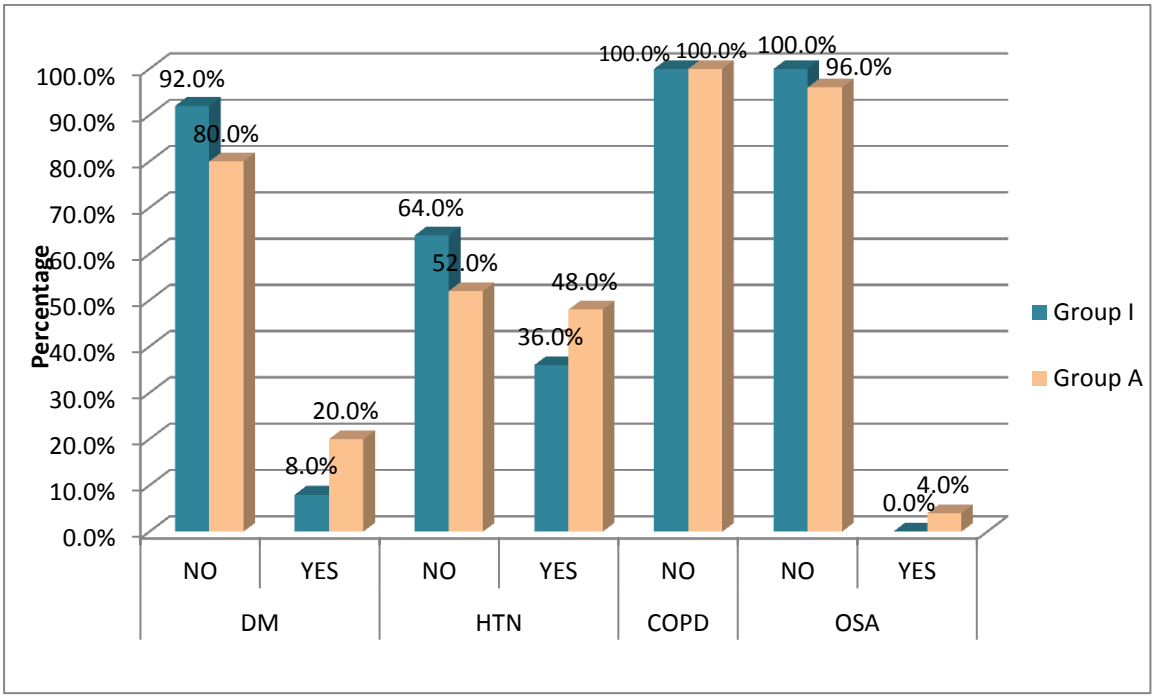


Figure 12: Distribution of patients according to Co-morbidities

Table 14 : Distribution of patients according to the criteria for successful placement of LMA

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Visible chest rise	YES	25	100.0%	25	100.0%	50		
Bilateral equal chest auscultation	YES	25	100.0%	25	100.0%	50		
Appearance of EtCO2 waveform	YES	25	100.0%	25	100.0%	50		
Successful placement of LMA	YES	25	100.0%	25	100.0%	50		
Total		25	100.0%	25	100.0%	50		

The parameters of successful insertion of LMA studied were visible chest rise, bilaterally equal chest auscultation and appearance of a square waveform EtCO2.

The two groups were comparable in terms of parameters of successful placement of LMA, that is, visible chest rise, bilateral equal chest auscultation, appearance of EtCO2 waveform and successful placement of LMA. Successful placement of LMA was present in all patients in both groups.

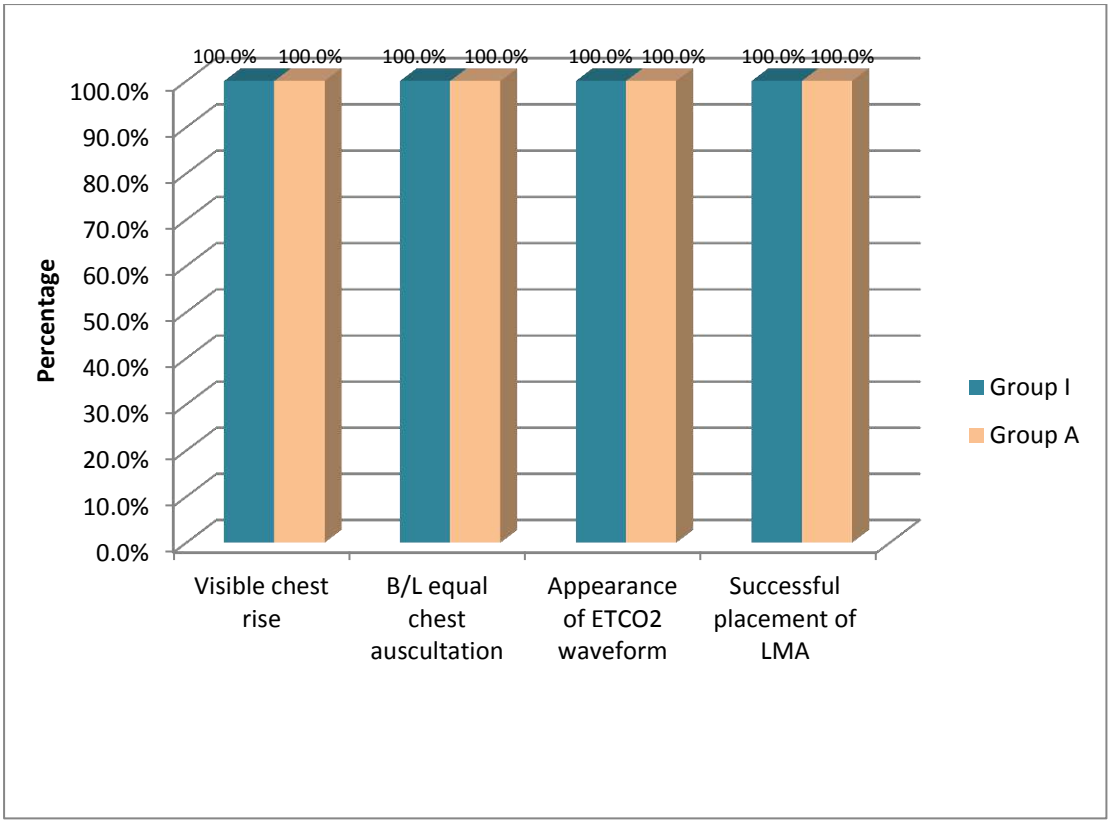


Figure 13: Distribution of patients according to the criteria for successful placement of LMA

Table 15: Distribution of patients according to mean insertion time

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
Insertion Time (sec)	22.20	3.91	21.96	2.46	-0.236	0.814

The mean time of insertion of SGA in both the groups was statistically non-significant with p- value being 0.814. In Group I, the mean insertion time was 22.20 ± 3.91 seconds and in that of Group A was 21.96 ± 2.46 seconds.

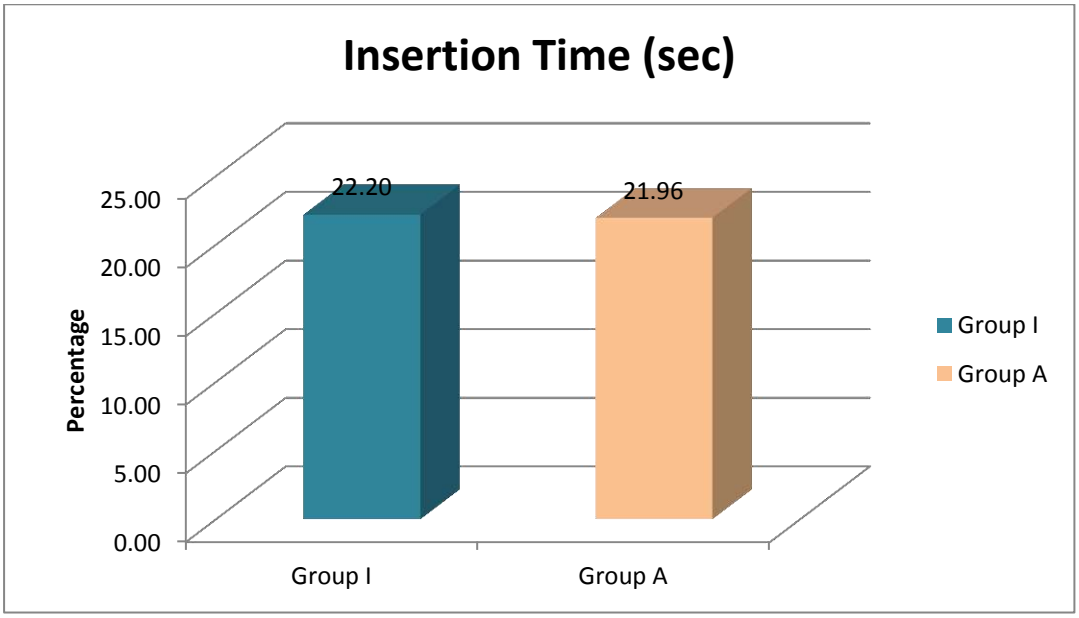


Figure 14: Distribution of patients according to mean insertion time

Table 16: Distribution of patients according to attempts for insertion of LMA

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Attempts	1	24	96.0%	24	96.0%	48	0.001	1.000
	2	1	4.0%	1	4.0%	2		
Total		25	100.0%	25	100.0%	50		

Total number of attempts required for successful placement in both the groups were comparable. Successful placement of LMA in first attempt was observed in 96% of the patients in both groups whereas second attempt was required in 4% of patients in both groups.

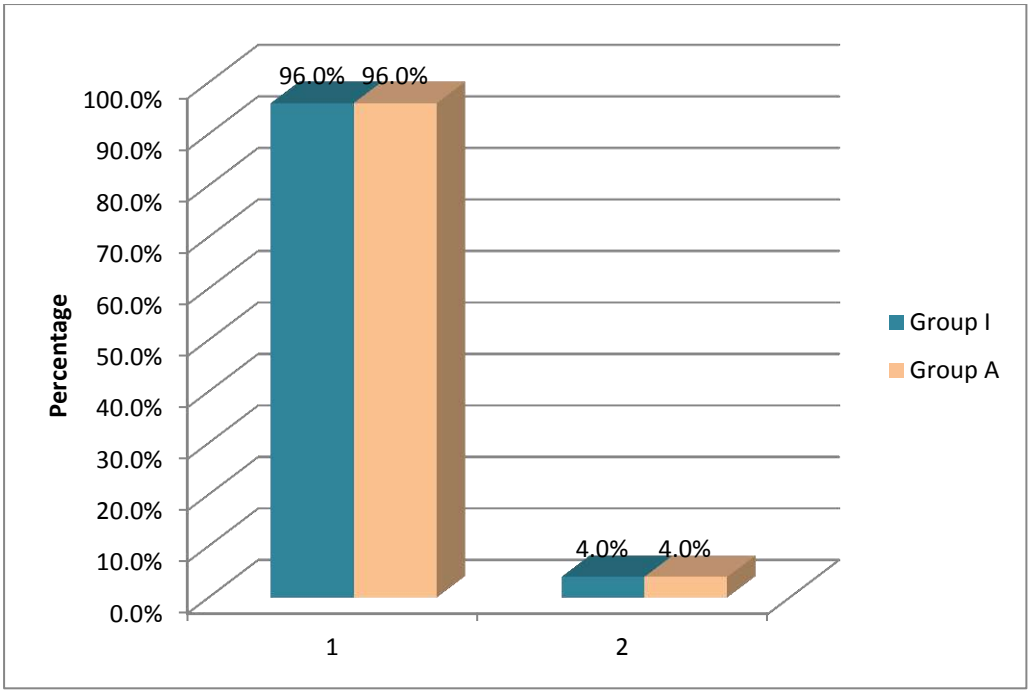


Figure 15: Distribution of patients according to attempts for insertion of LMA

Table 17: Distribution of patients according to change in size and type of LMA required

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Change in size of device	NO	25	100.0%	25	100.0%	50		
Size of device changed	N/A	25	100.0%	25	100.0%	50		
Change in type of device	NO	23	92.0%	24	96.0%	47	0.355	0.552
	YES	2	8.0%	1	4.0%	3		
Total		25	100.0%	25	100.0%	50		

There was no change in size of device required in both the groups.

The change in type of device required for both the groups were comparable. 8% of patients in Group I and 4% of patients in Group A required change in type of device.

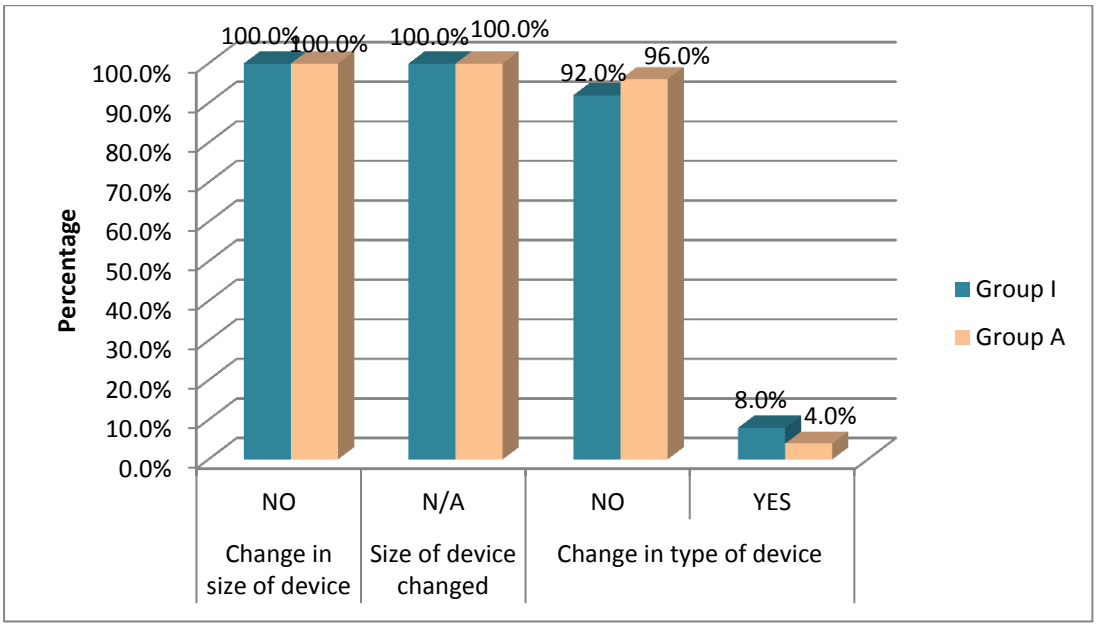


Figure 16: Distribution of patients according to change in size and type of LMA required

Table 18 : Distribution of patients according to manipulations done to adjust LMA

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Manipulations done to adjust LMA	NO	3	12.0%	6	24.0%	9	1.22	0.269
	YES	22	88.0%	19	76.0%	41		
Total		25	100.0%	25	100.0%	50		

The manipulations done to adjust LMA in both groups were comparable. 88% of patients in Group I and 76% of patients in Group A required manipulations to insert and adjust LMA

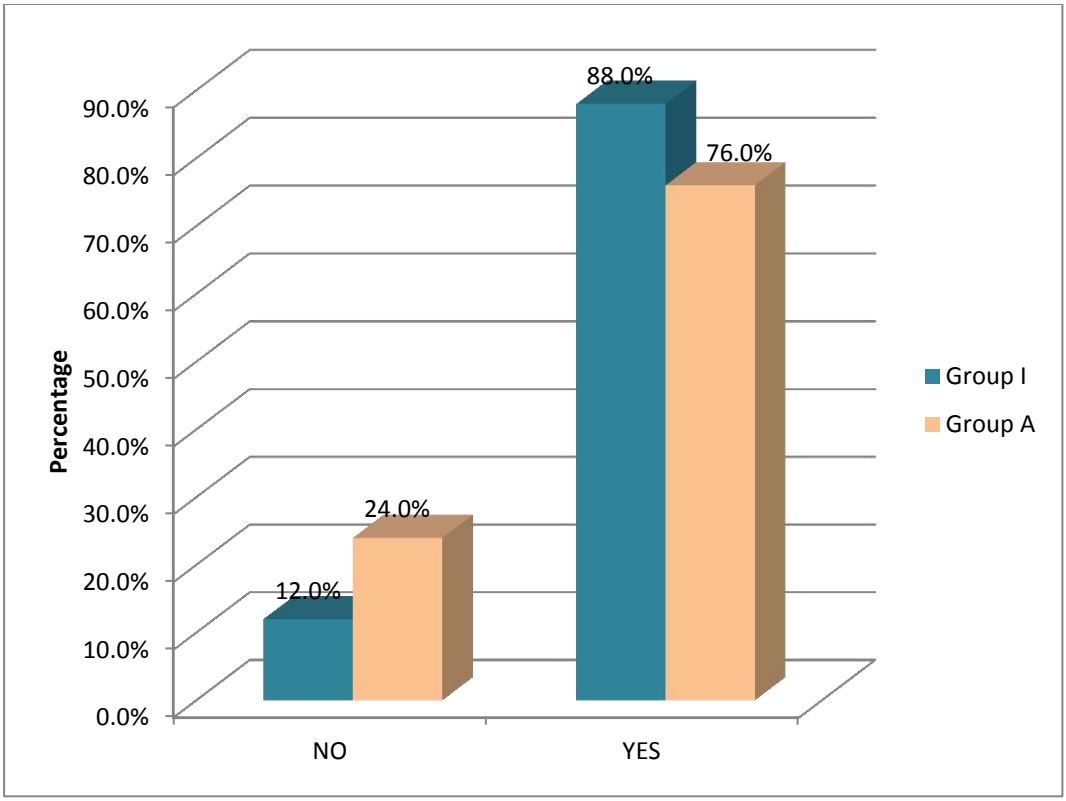


Figure 17: Distribution of patients according to manipulations done to adjust LMA

Table 19 : Distribution of patients according to type of manipulations done to adjust LMA

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Type of manipulation	Head tilt	0	0.0%	1	4.0%	1	3.915	0.562
	Head tilt, Chin lift, Jaw thrust	8	32.0%	5	20.0%	13		
	Head tilt, Jaw thrust	4	16.0%	4	16.0%	8		
	Head tilt, Chin lift	10	40.0%	8	32.0%	18		
	Jaw thrust	0	0.0%	1	4.0%	1		
	N/A	3	12.0%	6	24.0%	9		
Total		25	100.0%	25	100.0%	50		

The manipulations performed to adjust LMA included head tilt, chin lift and jaw thrust. The type of manipulations required in both the groups were comparable. All the three manipulations, including head tilt, chin lift and jaw thrust were required and performed in 32% of patients in Group I and 20% of patients in Group A. Head tilt and jaw thrust were performed in 16% of patients in Group I and 16% of patients in Group A. Head tilt with chin lift were performed in 40% of patients in Group I and 32 % of patients in Group A. No patient in Group I required only head tilt or jaw thrust. Head tilt alone was performed in 4% of patients in Group A. Similarly jaw thrust alone was performed in 4% of patients in Group A. 12% of patients in Group I and 24% of patients in Group A did not require any type of manipulations to adjust LMA.

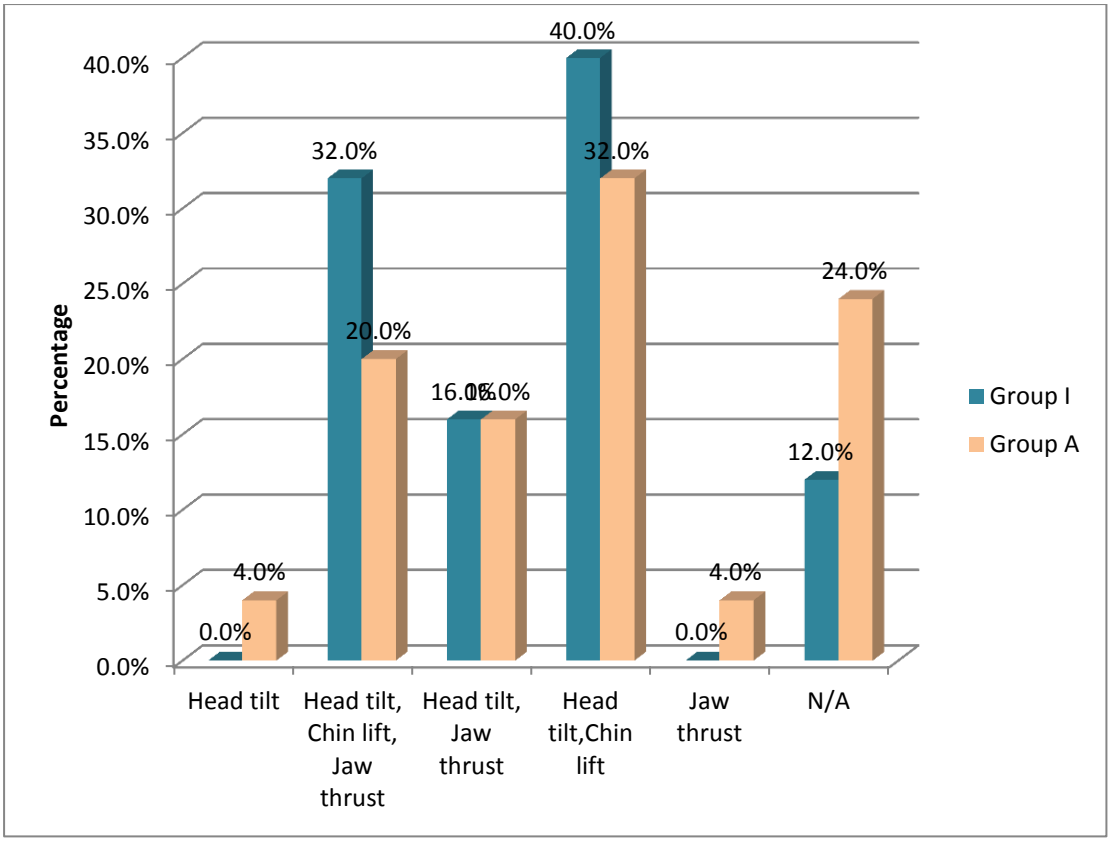


Figure 18 : Distribution of patients according to type of manipulations done to adjust LMA

Table 20: Distribution of patients according to attempts of gastric tube insertion

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Attempts of gastric tube insertion	1	23	92.0%	24	96.0%	47	1.021	0.600
	2	1	4.0%	1	4.0%	2		
	3	1	4.0%	0	0.0%	1		
Total		25	100.0%	25	100.0%	50		

Total number of attempts required for successful gastric tube insertion were comparable in both the groups. 92% of patients in Group I and 96% of patients in Group A had successful insertion of gastric tube in first attempt whereas 4% patients in both groups required second attempt and 4% patients in Group I required third attempt.

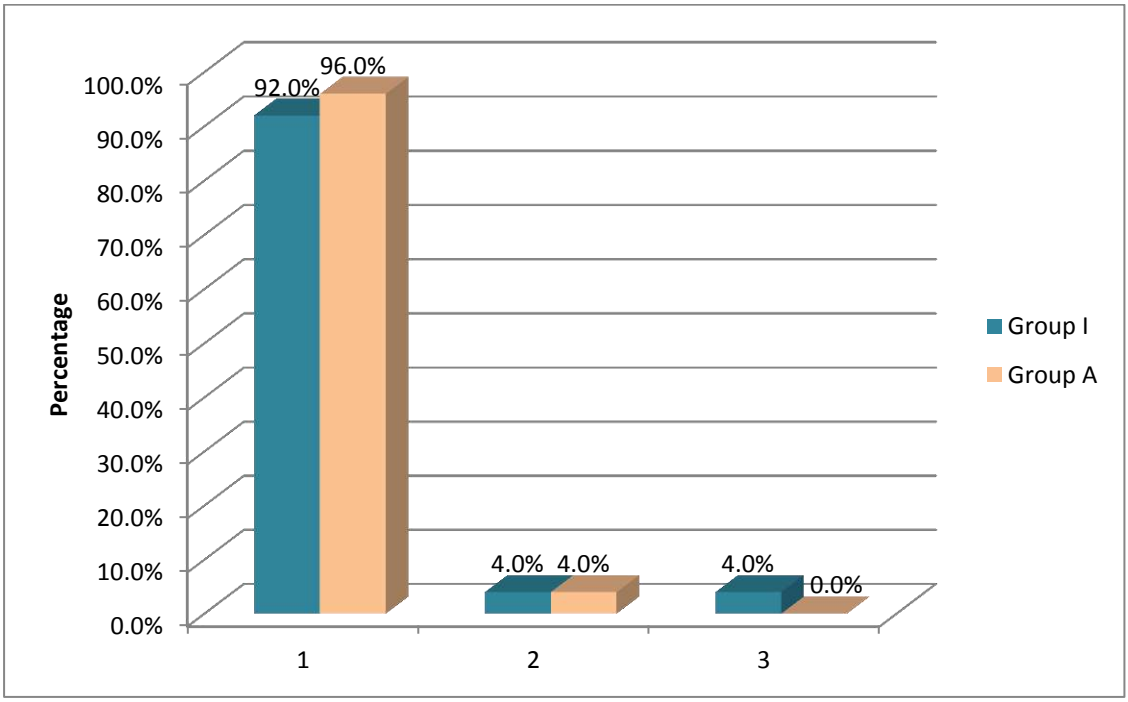


Figure 19 : Distribution of patients according to attempts of gastric tube insertion

Table 21 : Distribution of patients according to mean of attempts of gastric tube insertion

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
Attempts of gastric tube insertion	1.12	0.44	1.04	0.20	0.828	0.412

The mean of gastric tube insertion attempts in both groups were comparable. In Group I, the mean of total attempts was 1.12 ± 0.44. In Group A, the mean of total attempts was 1.04 ± 0.20.

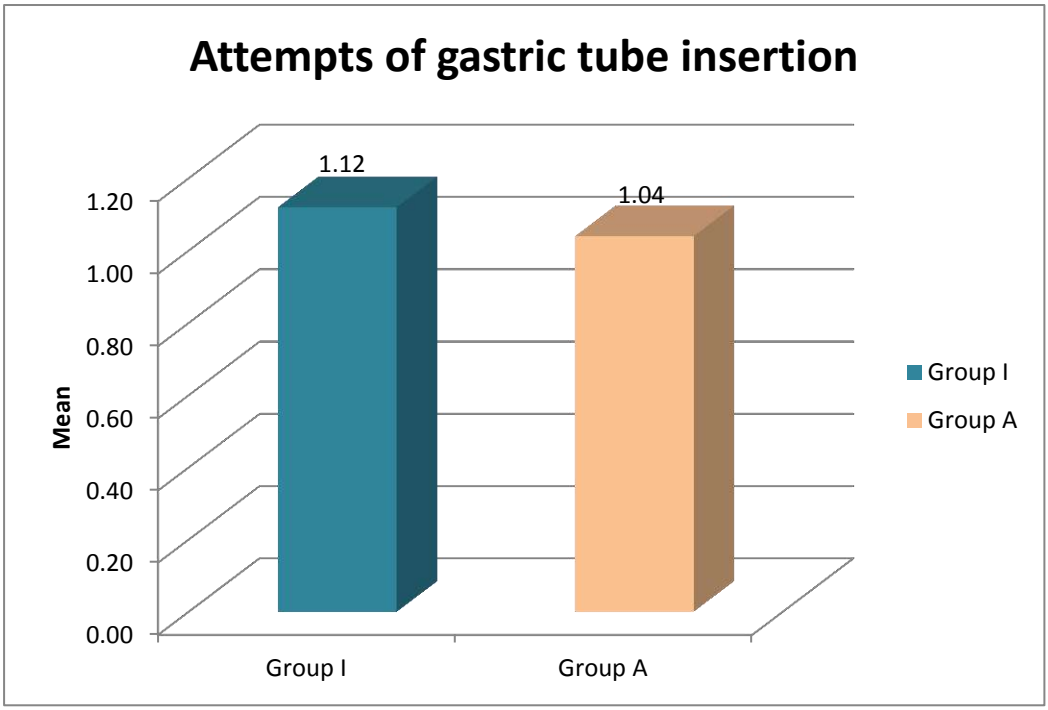


Figure 20: Distribution of patients according to mean of attempts of gastric tube insertion

Table 22 : Distribution of patients according to ease of insertion of LMA

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Ease of insertion of LMA	Difficult	6	24.0%	4	16.0%	10	1.432	0.489
	Easy	3	12.0%	6	24.0%	9		
	Moderate	16	64.0%	15	60.0%	31		
Total		25	100.0%	25	100.0%	50		

The difficulty of insertion as graded by the anaesthesiologist inserting the device for Group I was easy in 12%, moderate in 16% and difficult in 24% of the patients while in Group A it was easy in 24%, moderate in 60% of the patients and difficult in 16% of the patients. The results of the two groups were comparable and not statistically significant.

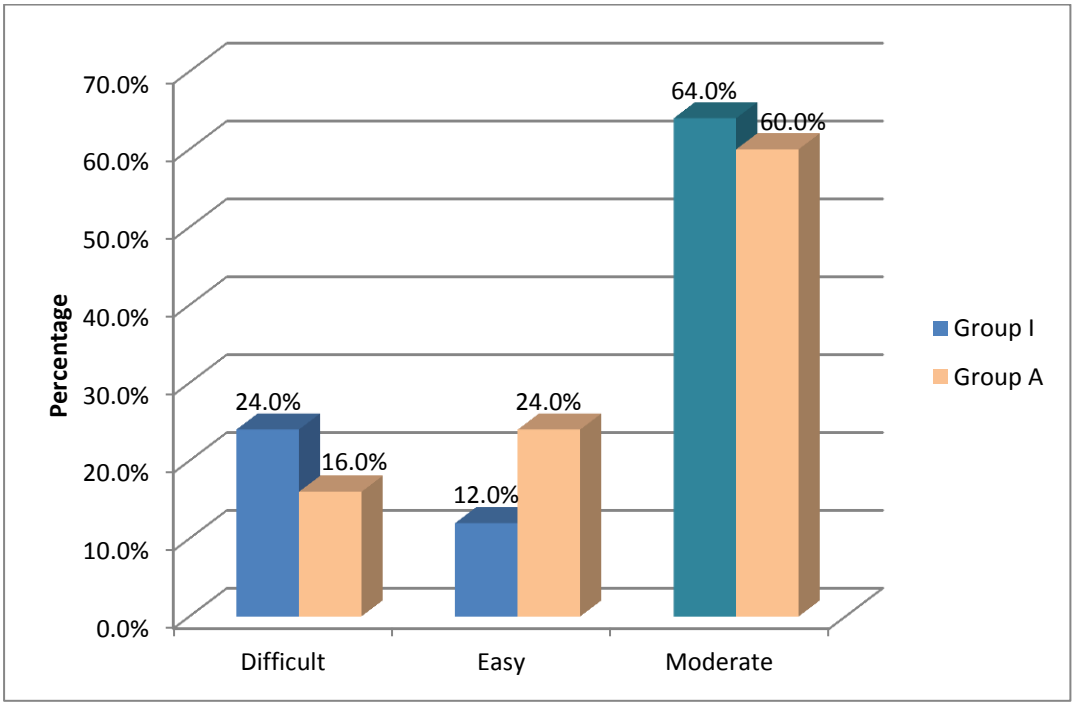
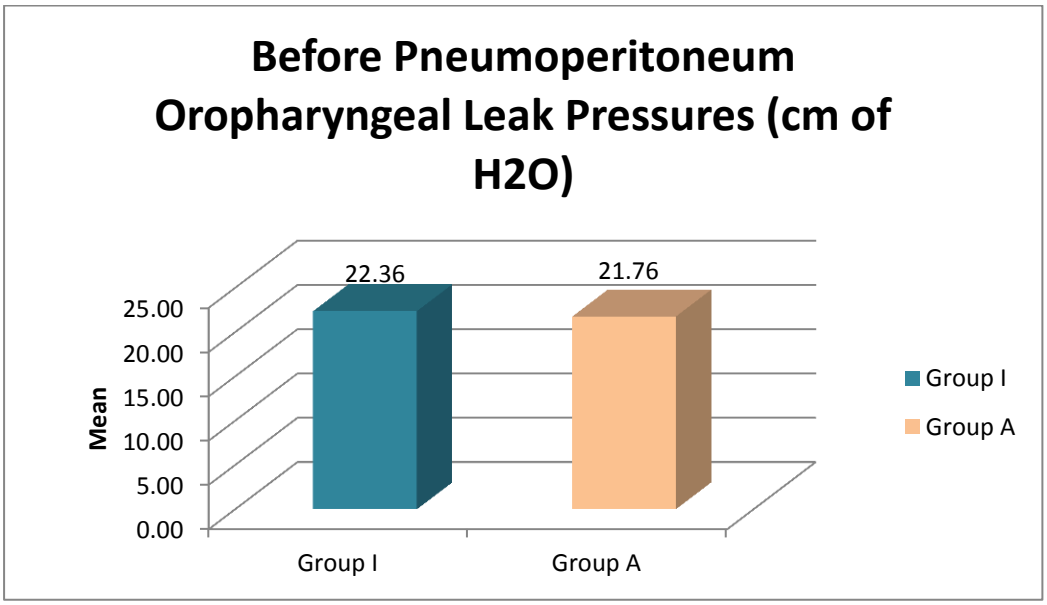


Figure 21 : Distribution of patients according to ease of insertion of LMA

Table 23: Distribution of patients according to Oropharyngeal Leak Pressures (OLP) before and after pneumoperitoneum (cm of H2O)

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
Before Pneumoperitoneum Oropharyngeal Leak Pressures (cm of H2O)	22.36	4.02	21.76	4.26	-0.468	0.640
After Pneumoperitoneum Oropharyngeal Leak Pressures (cm of H2O)	26.92	4.41	26.38	3.83	-0.352	0.725

The OLP before and after pneumoperitoneum of both the groups were comparable. There was no statistically significant difference in the OLP values of both the groups. The mean OLP of Group I before pneumoperitoneum was 22.36 ± 4.02 cm of H2O and that of Group A was 21.76 ± 4.26 cm of H2O. The mean OLP of Group I after pneumoperitoneum was 26.92 ± 4.41 cm of H2O and that of Group A was 26.38 ± 3.83 cm of H2O.



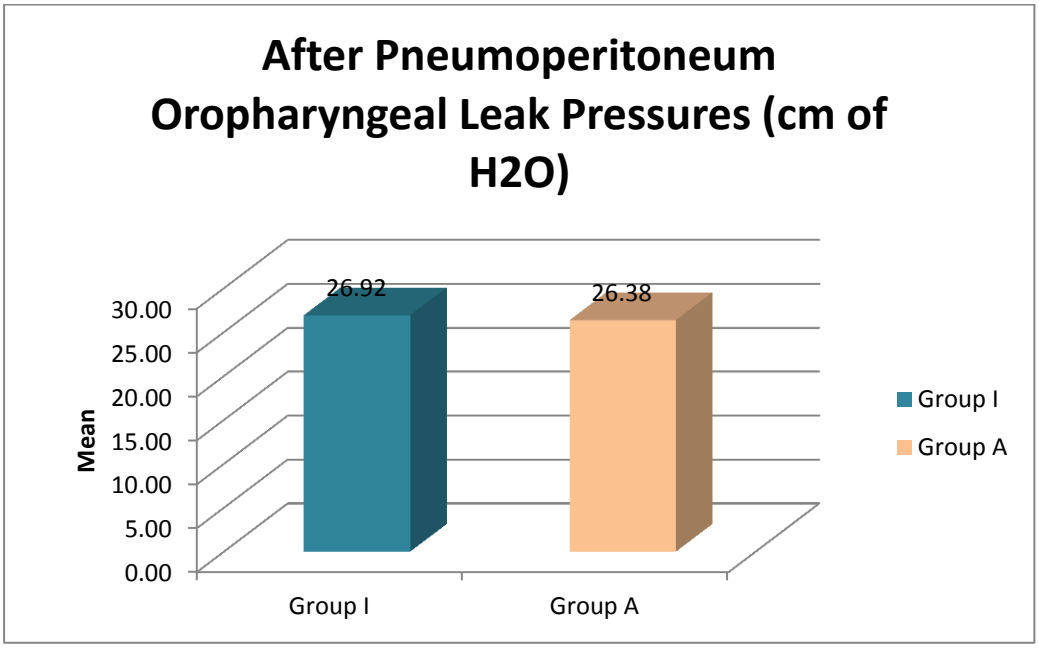


Figure 22: Distribution of patients according to Oropharyngeal Leak Pressures before and after pneumoperitoneum (cm of H2O)

Table 24 : Distribution of patients according to occurrence of intraoperative desaturation episodes

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Desaturation episodes (SpO2< 90%)	NO	24	96.0%	24	96.0%	48	0.000	1.000
	YES	1	4.0%	1	4.0%	2		
Total		25	100.0%	25	100.0%	50		

The desaturation episodes occurring in both the groups were comparable. No episode of desaturation occurred in 96% of the patients in both groups whereas desaturation occurred in 4% of the patients in both the groups.

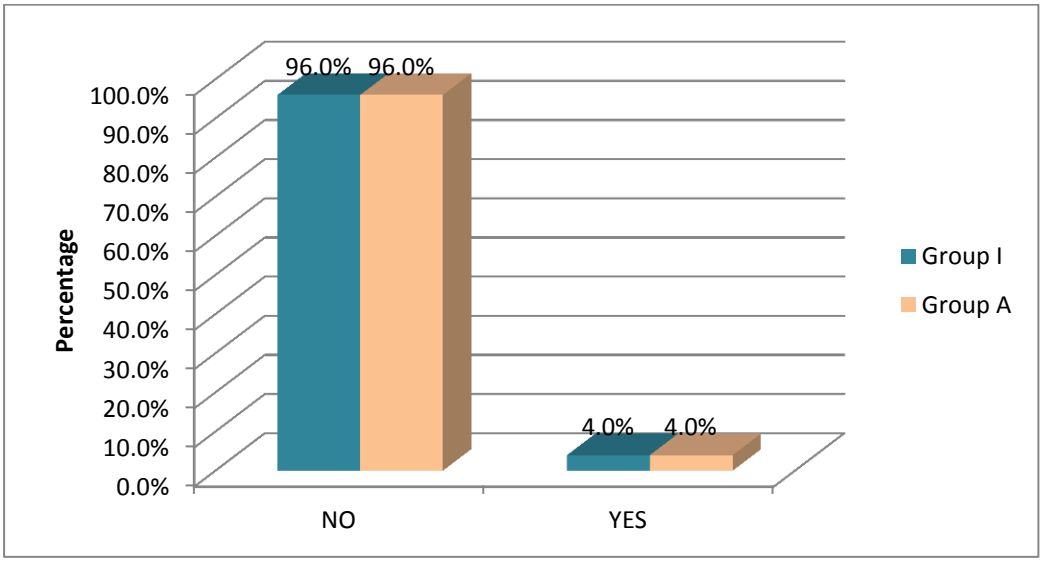


Figure 23: Distribution of patients according to occurrence of intraoperative desaturation episodes

Table 25 : Distribution of patients according to number of intraoperative desaturation episodes

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
No. of desaturation episodes	1	1	4.0%	1	4.0%	2	0.000	1.000
	N/A	24	96.0%	24	96.0%	48		
Total		25	100.0%	25	100.0%	50		

The number of desaturation episodes occurring in both the groups were comparable. Only 1 episode of desaturation was seen in 4% of the patients in both the groups. No episode of desaturation occurred in 96% of the patients in both groups.

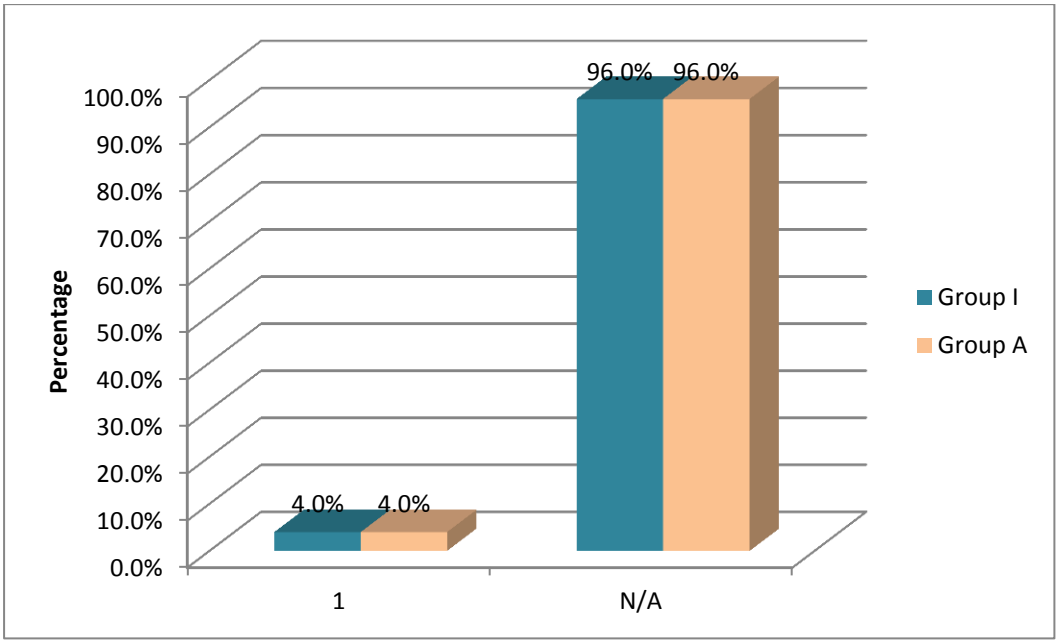


Figure 24: Distribution of patients according to number of intraoperative desaturation episodes

Table 26: Distribution of patients according to blood staining of LMA post-operatively

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Blood staining	NO	25	100.0%	25	100.0%	50		
Total		25	100.0%	25	100.0%	50		

The occurrence of blood staining of LMA in both the groups was comparable. No LMA was found to be blood stained after removal post-operatively in both the groups.

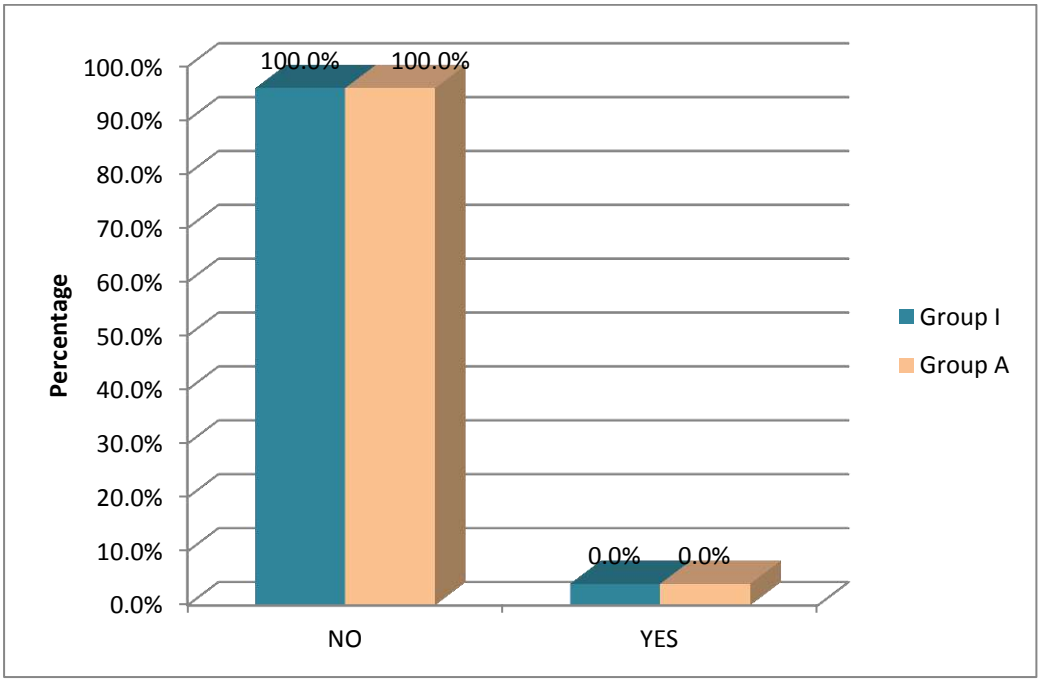


Figure 25: Distribution of patients according to blood staining of LMA post-operatively

Table 27: Distribution of patients according to dysphagia post-operatively

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Dysphagia	NO	18	72.0%	23	92.0%	41	3.388	0.066
	YES	7	28.0%	2	8.0%	9		
Total		25	100.0%	25	100.0%	50		

The occurrence of dysphagia after removal of LMA in post-operative period in both the groups was comparable. 28% of patients in Group I and 8% of patients in Group A complained of dysphagia in post-operative period.

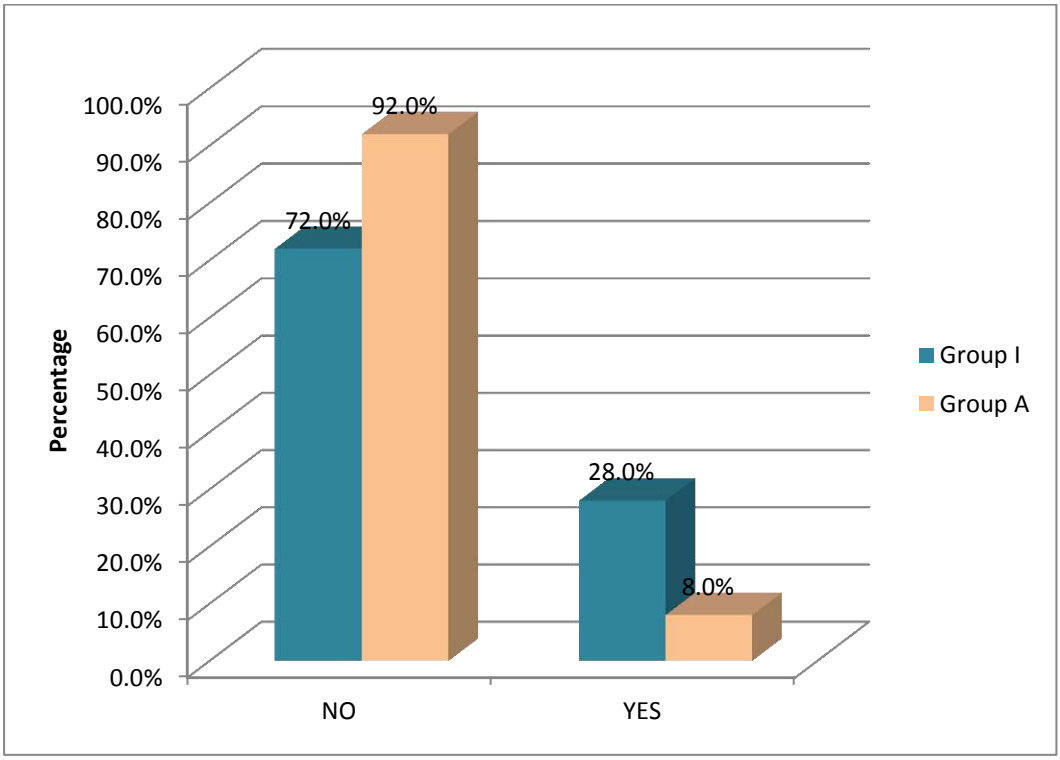


Figure 26 : Distribution of patients according to dysphagia post-operatively

Table 28 : Distribution of patients according to dysphonia post-operatively

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Dysphonia	NO	22	88.0%	24	96.0%	46	1.087	0.297
	YES	3	12.0%	1	4.0%	4		
Total		25	100.0%	25	100.0%	50		

The occurrence of dysphonia after removal of LMA in post-operative period in both the groups was comparable. 12% of patients in Group I and 4% of patients in Group A complained of dysphonia in post-operative period.

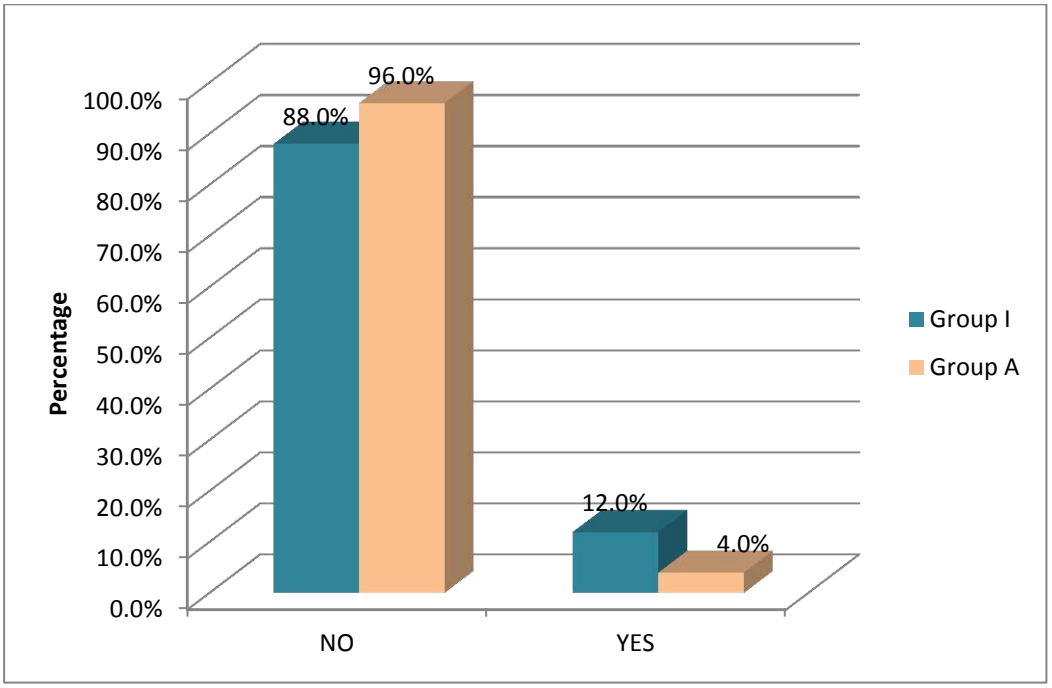


Figure 27 : Distribution of patients according to dysphonia post-operatively

Table 29: Distribution of patients according to sore throat rating scale

		Group I		Group A		Total	Chi-square value	p-value
		No. of cases	%age	No. of cases	%age			
Sore throat grade	0	11	44.0%	13	52.0%	24	3.767	0.583
	1	1	4.0%	1	4.0%	2		
	2	2	8.0%	2	8.0%	4		
	3	3	12.0%	6	24.0%	9		
	4	7	28.0%	3	12.0%	10		
	5	1	4.0%	0	0.0%	1		
Total		25	100.0%	25	100.0%	50		

The presence of sore throat was comparable between the two groups and was not found to be statistically significant.

Sore throat was not observed in 44% of patients in Group I and 52% of patients in Group A. Mild grade of Sore throat (1-3) was observed in 24% of the patients in Group I and 36% of the patients in Group A. Moderate grade of Sore throat (4-6) was observed in 32% of the patients in Group I and 12% of the patients in Group A.

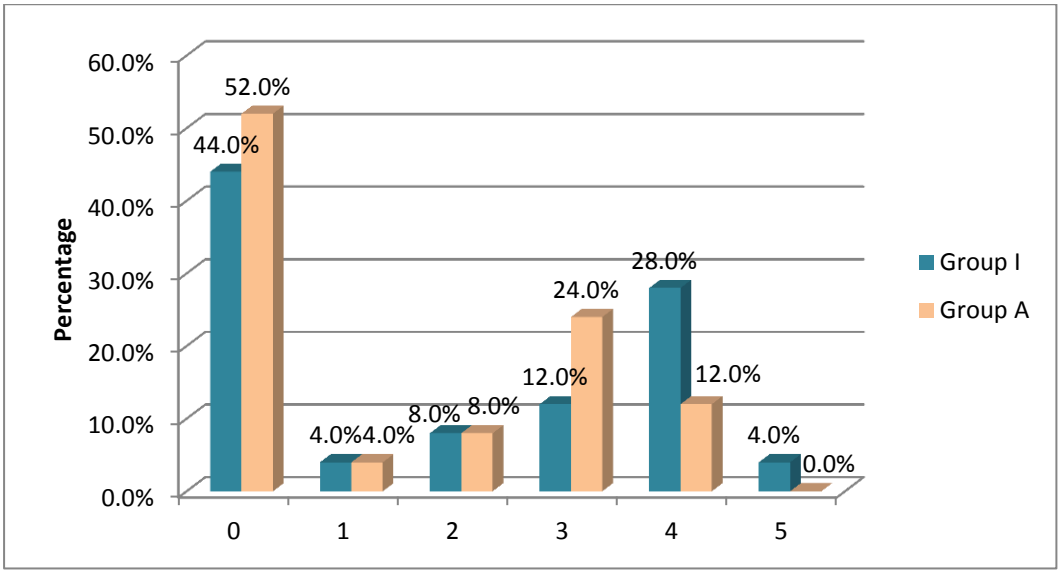


Figure 28: Distribution of patients according to sore throat rating scale

Table 30 : Distribution according to Heart Rate (beats/min)

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
HR_Baseline	77.00	11.93	79.08	10.92	-0.643	0.523
HR_Induction	86.12	10.73	85.48	8.18	0.237	0.813
HR_1 min	86.64	13.52	89.24	9.17	-0.796	0.430
HR_5 min	80.28	13.07	81.00	10.27	-0.217	0.829
HR_10 min	77.48	14.28	80.44	9.76	-0.856	0.396
HR_15 min	77.88	12.04	80.08	9.41	-0.720	0.475
HR_30 min	78.68	12.03	79.80	10.52	-0.350	0.728

The mean Heart Rate intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

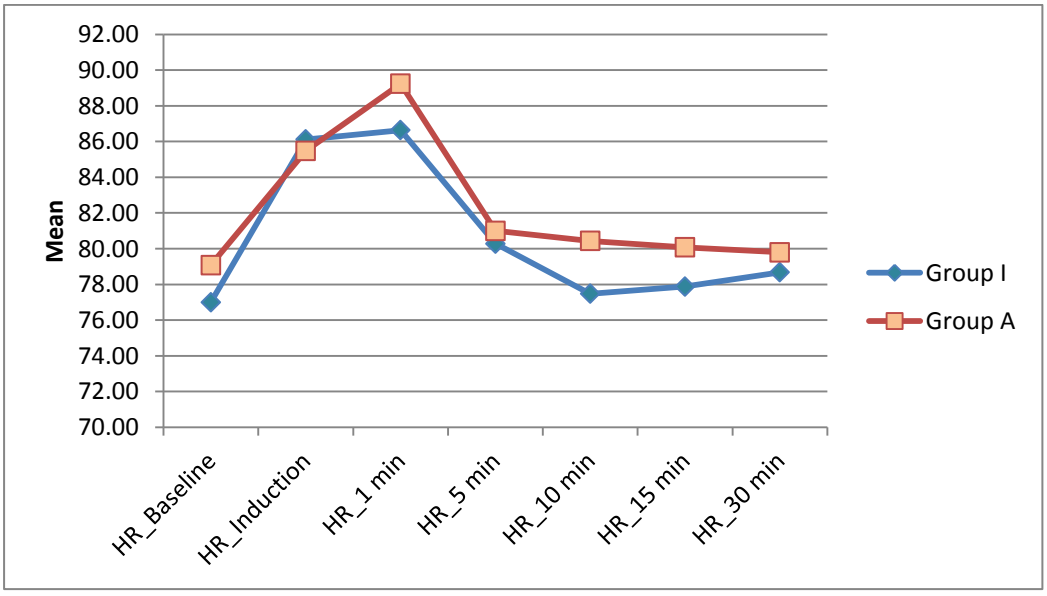


Figure 29: Distribution according to Heart Rate (beats/min)

Table 31: Distribution according to Systolic Blood Pressure (mm Hg)

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
SBP_Baseline	124.80	12.50	133.88	16.38	-2.203	0.032
SBP_Induction	121.84	18.87	131.12	16.87	-1.833	0.073
SBP_1 min	114.92	20.68	122.04	23.59	-1.135	0.262
SBP_5 min	123.24	15.89	129.52	16.98	-1.350	0.183
SBP_10 min	128.28	18.02	133.40	15.73	-1.070	0.290
SBP_15 min	129.48	14.48	133.96	12.12	-1.186	0.241
SBP_30 min	125.48	14.00	133.64	11.77	-2.231	0.030

The mean Systolic Blood Pressure (SBP) intra-operatively at baseline for Group I was 124.80 ± 12.50 mm Hg and for Group A was 133.88 ± 16.38 mm Hg and was statistically significant with p-value being 0.032. However, the mean SBP at induction, 1 Minute, 5 Minutes, 10 Minutes and 15 Minutes post induction were comparable for both the groups and were statistically non-significant.

Thereafter, the mean SBP at 30 Minutes for Group I was 125.48 ± 14.00 mm Hg and for Group A was 133.64 ± 11.77 mm Hg and was statistically significant with p-value being 0.030.

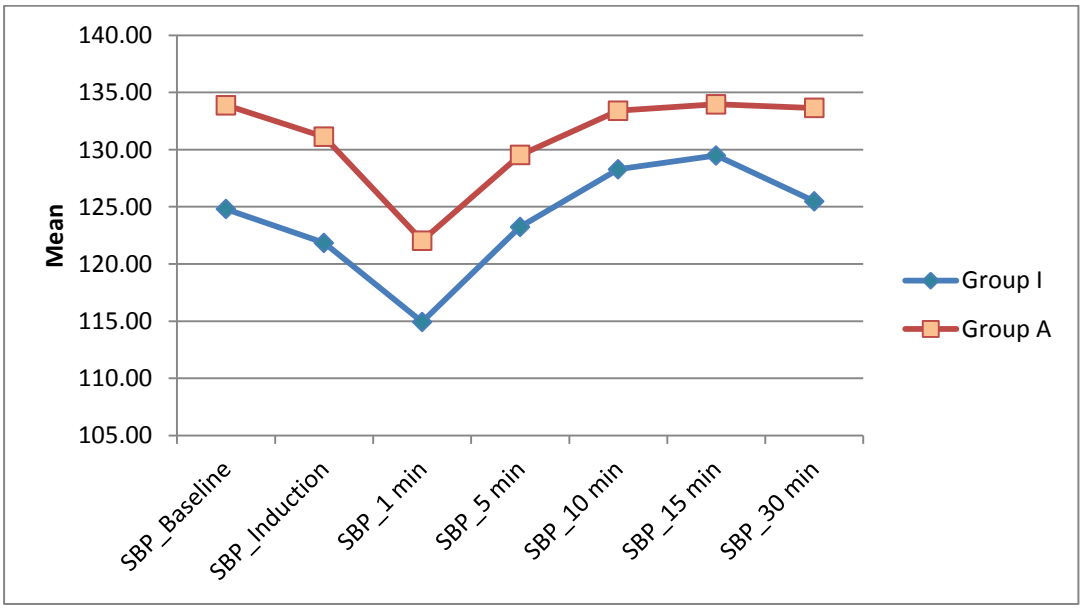


Figure 30: Distribution according to Systolic Blood Pressure (mm Hg)

Table 32: Distribution according to Diastolic Blood Pressure (mm Hg)

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
DBP_Baseline	80.20	9.04	84.00	10.69	-1.357	0.181
DBP_Induction	79.60	12.19	80.88	9.82	-0.409	0.684
DBP_1 min	73.88	13.75	75.72	15.28	-0.447	0.657
DBP_5 min	78.92	11.33	79.36	11.66	-0.135	0.893
DBP_10 min	81.28	14.70	82.40	11.14	-0.304	0.763
DBP_15 min	79.92	11.70	82.84	10.99	-0.909	0.368
DBP_30 min	77.88	11.78	81.52	10.14	-1.171	0.247

The mean Diastolic Blood Pressure intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

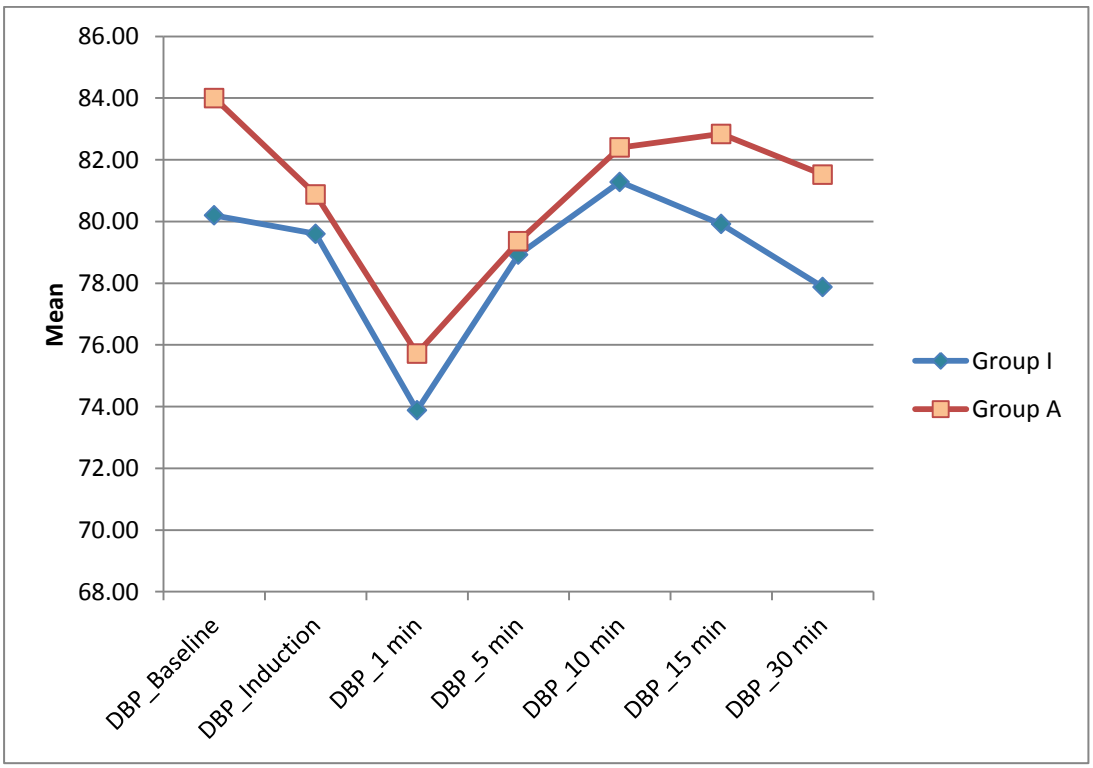


Figure 31: Distribution according to Diastolic Blood Pressure (mm Hg)

Table 33 : Distribution according to Oxygen Saturation (SpO2)

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
SPO2_Baseline	97.16	1.14	97.76	1.16	-1.238	0.216
SPO2_Induction	99.64	0.76	99.64	0.76	-0.201	0.841
SPO2_1 min	99.08	1.19	99.00	1.63	-0.261	0.794
SPO2_5 min	98.44	1.45	98.16	1.84	-0.320	0.749
SPO2_10 min	97.52	2.06	97.40	2.42	-0.039	0.969
SPO2_15 min	97.20	2.75	97.52	2.00	-0.099	0.921
SPO2_30 min	97.28	2.23	97.52	1.96	-0.286	0.775

The oxygen saturation intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

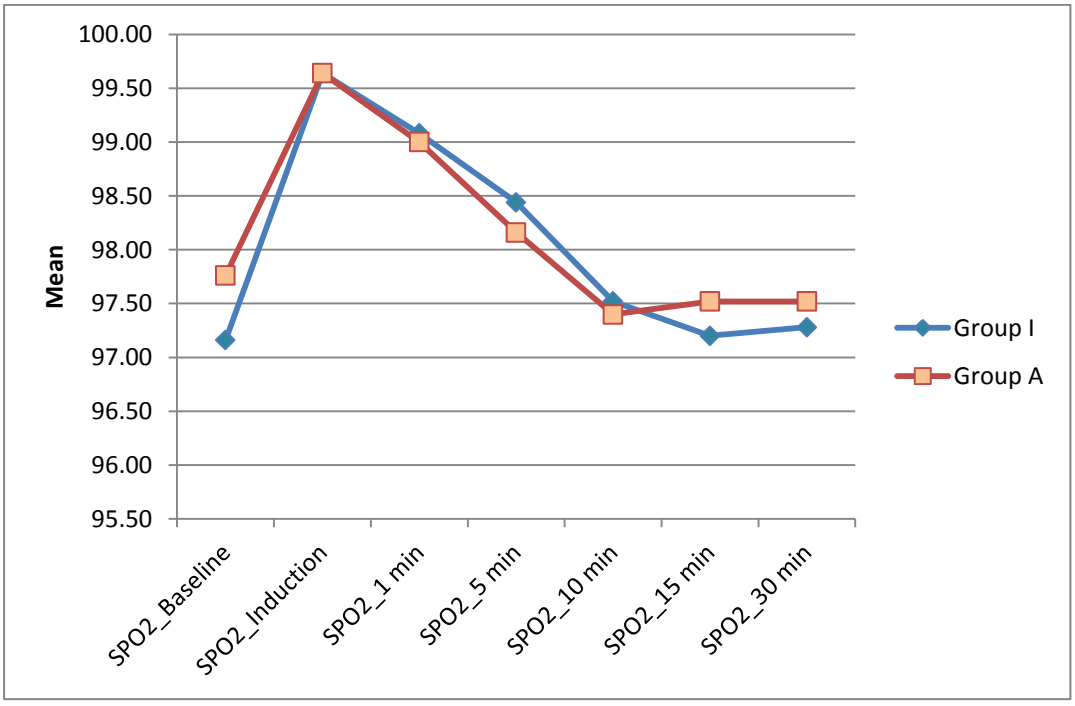


Figure 32 : Distribution according to Oxygen Saturation (SpO2)

Table 34: Distribution according to Expired Tidal Volume (ml)

	Group I		Group A		t	p-value
	Mean	SD	Mean	SD		
Expired Tidal Volume (ml)_Baseline	509.28	84.32	519.64	56.01	-0.512	0.611
Expired Tidal Volume (ml)_Induction	510.68	73.79	504.16	40.34	0.388	0.700
Expired Tidal Volume (ml)_1 min	484.16	49.33	474.84	84.29	0.477	0.635
Expired Tidal Volume (ml)_5 min	473.20	40.68	494.00	35.21	-1.933	0.059
Expired Tidal Volume (ml)_10 min	474.68	38.20	491.24	44.72	-1.408	0.166
Expired Tidal Volume (ml)_15 min	473.60	41.07	483.72	39.15	-0.892	0.377
Expired Tidal Volume (ml)_30 min	480.48	41.37	485.84	37.67	-0.479	0.634

The mean expired tidal volume intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

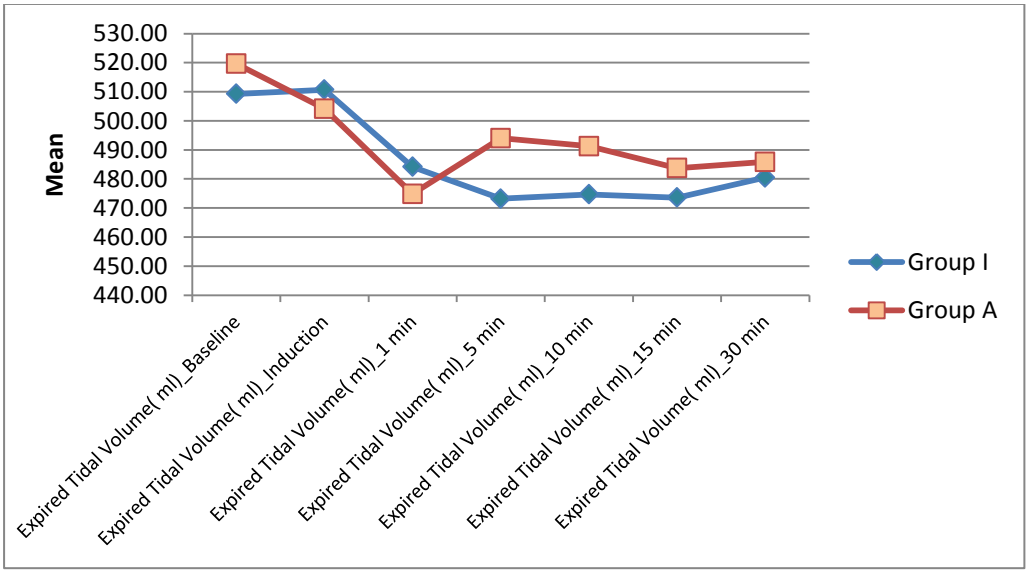


Figure 33: Distribution according to Expired Tidal Volume (ml)

Table 35: Distribution according to Peak Airway Pressures (cm of H2O)

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
Peak Pressures(cm of H2O)_Baseline	12.72	5.62	14.84	5.69	-1.452	0.147
Peak Pressures(cm of H2O)_Induction	15.52	4.67	17.72	5.44	-1.483	0.138
Peak Pressures(cm of H2O)_1 min	19.44	4.30	21.12	5.32	-0.973	0.330
Peak Pressures(cm of H2O)_5 min	22.36	3.84	23.32	5.82	-0.467	0.641
Peak Pressures(cm of H2O)_10 min	25.24	3.84	26.08	4.11	-0.488	0.625
Peak Pressures(cm of H2O)_15 min	25.52	3.92	26.68	4.05	-0.996	0.319
Peak Pressures(cm of H2O)_30 min	25.12	4.31	26.40	3.87	-1.475	0.140

The mean Peak Airway Pressures intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

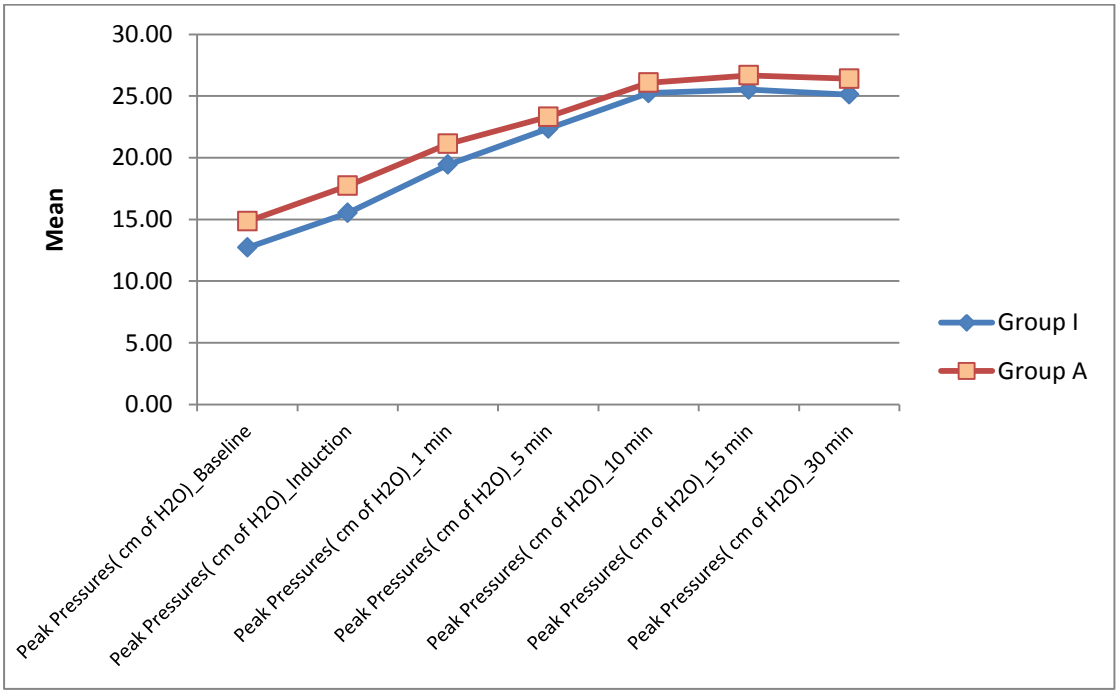


Figure 34: Distribution according to Peak Airway Pressures (cm of H2O)

Table 36: Distribution according to Plateau Pressures (cm of H2O)

	Group I		Group A		Z	p-value
	No. of cases	%age	No. of cases	%age		
Plateau Pressures(cm of H2O)_Baseline	10.76	5.86	12.36	5.42	-1.190	0.234
Plateau Pressures(cm of H2O)_Induction	13.84	4.96	15.52	5.46	-1.212	0.225
Plateau Pressures(cm of H2O)_1 min	17.56	4.44	19.00	4.65	-1.278	0.201
Plateau Pressures(cm of H2O)_5 min	20.32	4.50	20.68	5.34	-0.263	0.792
Plateau Pressures(cm of H2O)_10 min	23.32	3.67	23.32	3.99	-0.234	0.815
Plateau Pressures(cm of H2O)_15 min	23.12	3.84	24.04	3.46	-1.054	0.292
Plateau Pressures(cm of H2O)_30 min	23.00	4.09	23.68	3.25	-1.093	0.275

The mean Plateau Pressures intra-operatively at all intervals of observations was comparable between both the groups and was statistically non-significant.

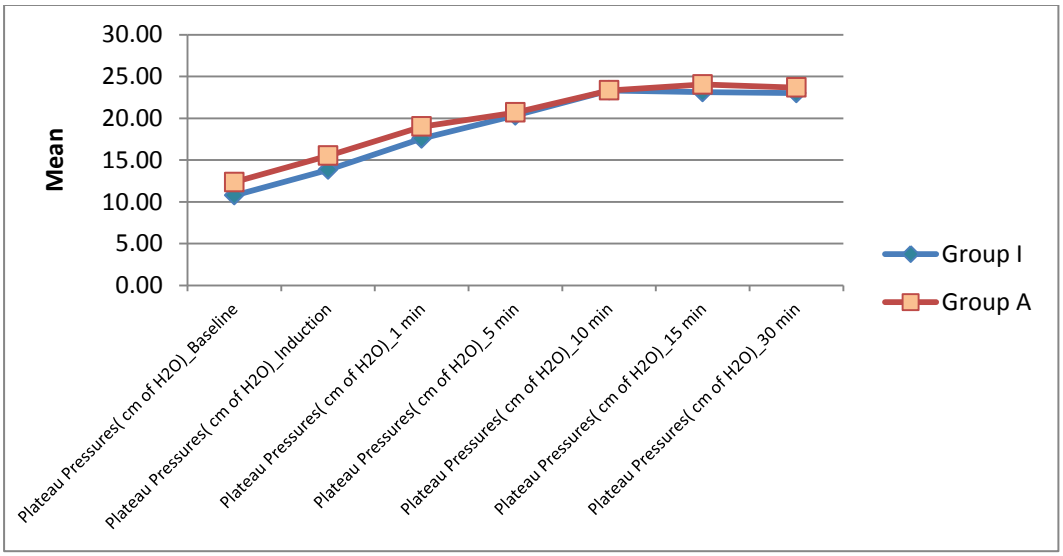


Figure 35: Distribution according to Plateau Pressures (cm of H2O)

Table 37: Distribution of patients according to End Tidal CO2 (mm Hg)

	Group I		Group A		Z	p-value
	Mean	SD	Mean	SD		
EtCO2(mm Hg)_Baseline	28.52	1.73	28.88	2.15	-0.752	0.452
EtCO2(mm Hg)_Induction	30.52	2.92	30.68	2.12	-0.853	0.394
EtCO2(mm Hg)_1 min	32.08	2.69	32.40	2.81	-0.531	0.596
EtCO2(mm Hg)_5 min	32.64	2.94	32.80	2.08	-0.293	0.769
EtCO2(mm Hg)_10 min	34.48	2.35	33.80	1.63	-1.241	0.215
EtCO2(mm Hg)_15 min	34.56	2.16	33.68	1.84	-2.049	0.040
EtCO2(mm Hg)_30 min	34.08	2.10	33.24	1.30	-2.202	0.028

The mean End Tidal CO2 (EtCO2) intra-operatively at baseline for Group I was 28.52 ± 1.73 and for Group A was 28.88 ± 2.15 and was statistically not significant.

Similarly, the mean EtCO2 at induction, 1 minute, 5 minutes and 10 minutes post induction were comparable for both the groups and were statistically non-significant.

Thereafter, the mean EtCO2 at 15 Minutes for Group I was 34.56 ± 2.16 mm Hg and for Group A was 33.68 ± 1.84 mm Hg and was statistically significant with p-value being 0.040.

Similarly, the mean EtCO2 at 30 Minutes for Group I was 34.08 ± 2.10 mm Hg and for Group A was 33.24 ± 1.30 mm Hg and was statistically significant with p-value being 0.028.

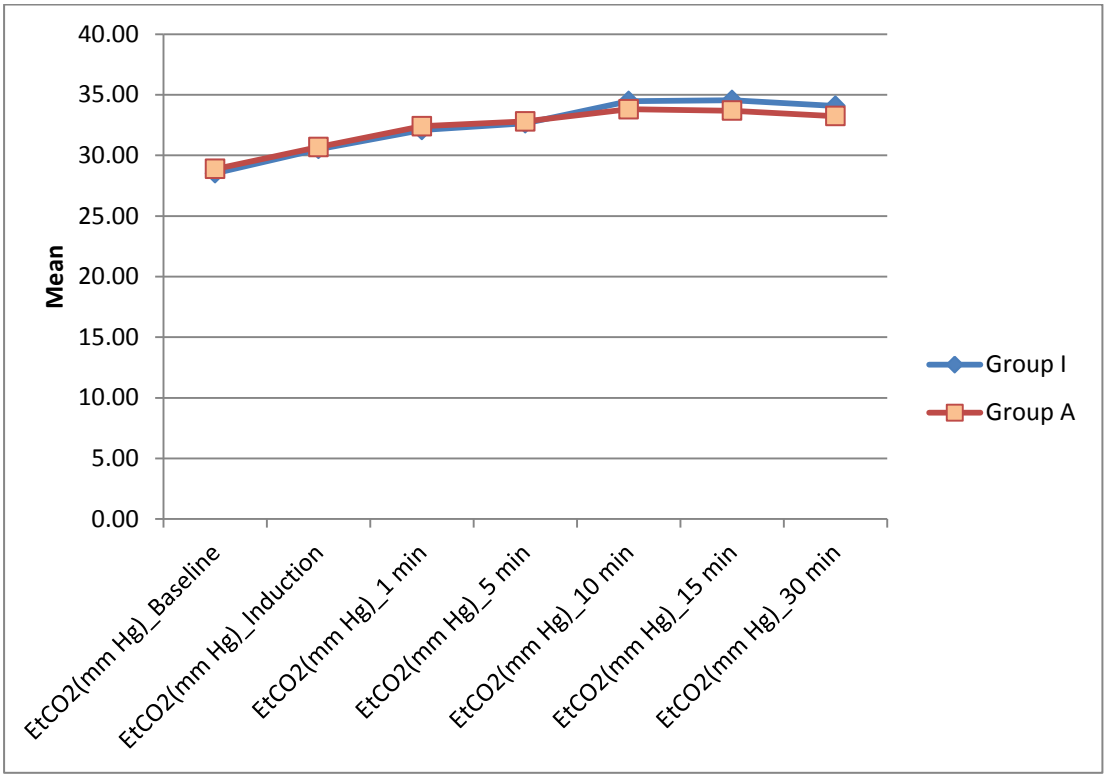


Figure 36: Distribution of patients according to End Tidal CO2 (mm Hg)

DISCUSSION

Obese patients are classically known to have anatomical as well as physiological difficult airway. With the increasing trend in prevalence of obesity, their airway becomes an important arena to be mastered by the anaesthesiologist.[14] In short surgical procedures and procedures where less fluctuations in haemodynamic variations are desired, airway can be easily secured by SADs. SADs have proven the test of time to secure airway and have proved to be beneficial in cases of difficult bag mask ventilation, difficult laryngoscopy and cannot ventilate cannot intubate scenarios, especially in obese patients. Thus SAD can be used to secure airway and prevent desaturation in obese patients. [5-9]

We conducted a prospective, randomised, single blinded comparative study to assess, evaluate and compare the clinical performance of two second generation SADs, I-Gel and Ambu AuraGain in obese patients. A second generation LMA, I-gel, has a soft gel like cuff made of thermoplastic elastomer which is soft, transparent, gel like & designed to anatomically fit the perilaryngeal & hypolaryngeal structures, without any inflatable cuff. [15] Ambu Aura Gain is also a second generation novel cuffed SGA, made of polyvinyl chloride, which has a preformed curve, bite block & also a built in gastric port. [4] It also has a thin and soft cuff which helps in providing a good seal thus preventing gastric regurgitation and aspiration.[18]

We compared I-Gel and Ambu AuraGain in terms of oropharyngeal leak pressures, time and ease of insertion, number of attempts required for insertion, manipulations required to adjust LMA, haemodynamic changes, respiratory parameters and complications if any in our obese subset of population.

Our both groups were comparable in terms of demographic data i.e. gender, age, BMI, height, weight, ASA grading and airway assessment.

The mean BMI of Group I was 33.60 ± 4.00 kg/m² and in Group B was 33.16 ± 3.90 kg/m².

In our study, we observed that the mean OLP of I-Gel before pneumoperitoneum was 22.36 ± 4.02 cm of H2O and that of Ambu AuraGain was 21.76 ± 4.26 cm of H2O. The mean OLP of I-Gel after pneumoperitoneum was 26.92 ± 4.41 cm of H2O and that of Ambu AuraGain was 26.38 ± 3.83 cm of H2O. The OLP before and after pneumoperitoneum of both the groups were comparable with p-value being 0.640 before pneumoperitoneum and 0.725 after pneumoperitoneum. Though we found no statistically significant difference in the OLP values of both the LMAs, but I-Gel had a slightly higher OLP values. Similarly, Chatterjee R et al in their comparative evaluation of I-Gel with Ambu AuraGain in paediatric patients, found that I-Gel demonstrated significantly higher leak pressures after insertion and after 30 minutes of insertion in paediatric patients as compared to Ambu AuraGain. They found that higher OLP in I-gel could be attributed to its non inflatable and soft gel-like cuff which sits adequately onto the supraglottic area of each individual patient [38] . Similar findings were noted by Theiler LG et al in their comparative study of I-Gel with Ambu Auraonce. They found that the OLP were significantly higher for I-Gel as compared to Ambu Auraonce [35]. Kim HJ et al conducted a study comparing Ambu AuraGain and I-gel in young paediatric patients, also observed similar results. They found that I-gel had significantly higher oropharyngeal leak pressures than Ambu AuraGain at one minute and ten minutes. [29]

However, in our study, OLP values were higher ,but there was no significant difference in both the groups. This can also be attributed to the fact that we conducted our study in obese patients with BMI> 30 kg/m^2. Obese individuals have excessive fatty tissue fold in mouth, pharynx, neck and increased posterior cervical, suprasternal, presternal fat and a very thick submental fat pad. Increased mucosal adipose tissue in obese patients contribute to better fit and seal as

there is less space left between LMA device and mucosal tissue and thereby less chances of leak. [14]

All these factors may have led to proper and adequate fit of I-Gel's thermoelastomer cuff and AuraGain's preformed curve, thus explaining high and comparable OLPs between the two groups. This reason can be supported by the study reported by Prabha R et al, who conducted a study to compare I-Gel in obese and non-obese patients. They found slightly higher OLP in obese patients (27.38 ± 4.38 cm H2O) as compared to non-obese patients (25.38 ± 4.79 cm H2O) but the difference was non-significant (p-value being 0.227). They attributed this difference to the fact that obese patients have increased fat deposition in perilaryngeal and hypolaryngeal soft tissues. Due to this, excess perilaryngeal soft tissues press onto the cuff of I-Gel more efficiently against the laryngeal inlet, thereby leading to better seal between the I-Gel and laryngeal inlet in obese patients and hence higher OLP. [31] These results are in accordance with our study. Thus we infer that higher OLP are achieved with LMA in obese patients. This factor also decreases the chances of aspiration. Similar results were observed in a study reported by Shariffuddin et al, who conducted a study to assess the clinical performance of LMA Protector in moderately obese patients. They found high OLP values (31.8 cm H2O) in obese patients. They attributed this to the fact that increased hypolaryngeal soft tissue adiposity might render the SAD device a snugger fit in obese patients. [46] Likewise, Weber U et al. also found that the OLP was higher in patients with moderate obesity than the patients with mild obesity. [43]

I-Gel thermoelastomer expands and takes the shape of hypopharyngeal tissues. [15] Similarly Ambu AuraGain has a built in inflatable cuff, that can be inflated for adequate fit over perilaryngeal tissues. [4] Lee JH et al conducted a study comparing I-Gel with Ambu AuraGain in paediatric patients undergoing elective surgeries and found no statistical difference in OLP of I-Gel and AuraGain

immediately after insertion and after 10 minutes of insertion. The initial OLP of the I-Gel and AuraGain were 25.0 ± 8.0 and 27.5 ± 7.7 cm H2O, respectively with p value being 0.130. [39] A randomised study comparing I-gel, Supreme LMA and Ambu AuraGain was conducted in non-obese patients undergoing laparoscopic surgeries. They found a statistically significant difference between the three LMAs with the mean OLP of 25.17 ± 3.24 cm H2O in I-gel, 24.37 ± 1.99 cm H2O in Supreme LMA and 29.63 ± 3.56 cm H2O in Ambu AuraGain. [11]

Though after thorough search of literature , we could not find enough studies in obese population , but many studies were conducted in paediatric population. On comparing both we could justify that obese and paediatric airway have certain similarities making them both anatomical and physiological difficult airway. The presence of large occiput in infants and children causes difficulty in flexion, similarly the hump at the nape of neck in obese causes difficulty in flexion. The tongue is large as compared to oral cavity and takes up more space making it difficult to sweep laryngoscope blade which can also be seen in obese patients as they have large tongue and increased fatty tissue inside oral cavity leading to narrowing of mouth opening due to large pool of buccal fat. Physiologically, the higher oxygen consumption due to higher basal metabolism and low residual volume of lungs can lead to rapid desaturation in children. Similarly obese patients have more oxygen consumption due to high adipose tissue and basal atelectasis and tend to desaturate early. Thus we can imply that paediatric airway is more or less as difficult as obese airway. [45]

In our study, on comparing both the LMAs, we found that I-Gel took slightly longer time (22.20 ± 3.91 seconds) to insert as compared to Ambu AuraGain (21.96 ± 2.46 seconds) but the mean time of insertion in both the groups was statistically non-significant with p-value being 0.814. The slight difference can be ascribed to the fact that Ambu AuraGain has a preformed built-in curve which allows easier insertion and hence less time to insert whereas it took more time to insert the

bulkier body of I-Gel. Our study is in consensus with the study by Prabha R et al, who found longer insertion time for I-Gel (17.19 ± 6.25 sec) in obese population as compared to non-obese population (16.19 ± 6.89 sec) but the difference was statistically not significant (p-value being 0.670). They rendered this small difference to the same reason of difficult airway in obese patients, hence longer time to insert. This comparable insertion time profile of I-Gel between obese and non-obese patients, is reassuring and shows that there is no increased insertion difficulty and no increased insertion time in obese patients as compared to non-obese patients. Hence, we can safely use either I-Gel or Ambu AuraGain in obese patients without fear of desaturation due to longer insertion time. [31]

Successful placement of the device in first attempt was observed in 96% of the patients in both groups whereas second attempt was required in 4% of patients in both groups with p-value being 1.00. None of the groups had insertion failure. In our study, we concluded that both devices had equal incidence of first attempt successful placement and total number of attempts required for successful placement in I-Gel and Ambu AuraGain groups were comparable. The results of our study are in accordance with Lee JH et al, who observed that first attempt success rate was comparable between I-Gel and Ambu AuraGain, with rates of 100 % in I-Gel and 93.5% in AuraGain respectively in their subset of paediatric population. [39] Similarly, Chatterjee R et al observed that the first attempt success rate was higher with Ambu AuraGain as compared to I-Gel , however difference being statistically non significant, with a p-value of 0.53. [38]

Insertion of I-Gel was found to be easy in 12%, moderate in 16% and difficult in 24% of the patients, while insertion of Ambu AuraGain was found to be easy in 24%, moderate in 60% and difficult in 16% of the patients with p-value being 0.489 in our study population. Though the difference was statistically non- significant, we found easier insertion of Ambu AuraGain because of its built-in preformed curve. The better

ease of insertion being attributed to built-in preformed curve of AuraGain but the difference being non-significant, we concluded that the two groups were comparable in terms of ease of insertion of device. Ease of I-Gel insertion was found to be comparable in obese and non- obese patients in the study by Prabha R et al with easier insertion in non-obese group but with no statistical difference (p-value being 0.223). This difference was rendered to cervical and submental fat pad in obese patients, thus narrowing the airways. At the same time, this comparable difference confirms and reassures the safety profile of I-Gel LMA in obese patients. [31]

On comparing the number of attempts of gastric tube placement through both devices, we found that gastric tube was comparatively easier to insert through Ambu AuraGain as compared to I-Gel. This difference can be ascribed to the fact that Ambu AuraGain has a preformed curve and hence easier insertion of gastric tube along its curve. Similar to our study, Lee HJ et al found easier insertion of gastric tube in Ambu AuraGain in contrast to I-Gel in paediatric population, and the difference was found to be statistically significant with p-value being 0.039. They also observed that first attempt success rate of gastric tube insertion in Ambu AuraGain was higher. [39] In contrast to our study, Meenakshi Sumadevi Pradeep et al found difficult insertion of gastric tube in Ambu AuraGain as compared to I-Gel and LMA Supreme, but they found the difference to be statistically insignificant. [11]

On comparing the manipulations done during inserting LMA in our study, we found that 88% of patients in Group I and 76% of patients in Group A required manipulations to insert and adjust LMA with p-value being 0.269. Thus, in our study, the manipulations done to adjust LMA in both groups were comparable. Manipulations were in the form of head tilt, chin lift and jaw thrust. We inferred that obese patients required more manipulations for I-Gel insertion compared to Ambu AuraGain. This difference can be because of the fact that Ambu

AuraGain has a built-in preformed curve that is easier to insert and requires less number of manipulations to adjust. Also it has an inflatable cuff that allows better fit over perilaryngeal tissues. On the other hand, I-Gel has a comparatively straighter and semi rigid body with harder and bulkier cuff, which increases its need for manipulations and possibility of inadequate seal and tendency of slipping out in obese patients. Chatterjee R et al, in their subset of paediatric population, found that majority of cases did not require any manipulation. They also observed that in whatever small group of patients that required device manipulation, more number of I-Gel insertion required manipulations but the difference being statistically non significant (p-value=0.3). [38] Likewise in the study by Kim HJ et al comparing I-Gel and Ambu AuraGain in paediatric population, they also demonstrated that I-Gel insertion required significantly more number of additional airway manipulations during insertion, such as adjustment of head and neck position, depth of insertion or taping of device with p-value <0.001. [29] Similarly, Theiler LG et al also observed that more airway interventions were required while inserting I-Gel and the difference was significant with p-value being < 0.01. Lee HJ et al in their study, also observed, 8.5 % of I-Gel cases required additional manipulations, in contrast to 0 % cases of AuraGain (P = 0.038). [35]

In our study, we observed that the mean heart rate, mean diastolic blood pressure, oxygen saturation, expired tidal volume, peak airway and plateau pressures intra-operatively at all intervals of observations were comparable between both the groups and were statistically non-significant. The mean Systolic Blood Pressure (SBP) at baseline and at 30 minutes post induction was significantly higher for Ambu AuraGain than that of I-Gel with p-value being 0.032 and 0.030 respectively. The difference in baseline SBP can be because of the presence of already higher values of preoperative blood pressures in these individuals. Similarly, 30 minutes post induction SBP difference can be rendered to the same reason of higher baseline BP in such individuals. We observed that EtCO2 was found to be significantly higher in I-Gel as

compared to Ambu AuraGain at 15 and 30 minutes with p-value being 0.040 and 0.028 respectively. This can be attributed to the possibility of baseline higher EtCO2 levels in patients of that group because of CO2 retention due to obesity and baseline higher values of PaCO2. The other possibility can be higher inflation pneumoperitoneum pressures by surgical team. Also varying high degrees of pneumoperitoneum in such patients might have led to this difference. Meenakshi Sumadevi Pradeep et al in their study compared pre-insertion and post-insertion parameters including heart rate, systolic and diastolic blood pressures, mean arterial pressures and oxygen saturation and found no statistically significant difference in pre-insertion and post-insertion parameters studied in all 3 groups. [11] Similarly, Chatterjee R et al noted that the haemodynamic parameters in both groups were comparable, and the difference was not statistically significant. [38]

Post-operative complications were also observed for both the groups. Only 1 episode of desaturation was seen in 4% of the patients in each group. No LMA was found to be blood stained after removal in both the groups. Dysphagia was reported in 28% of patients after I-Gel and 8% of patients after Ambu AuraGain. Similarly 12% of patients after I-Gel and 4% of patients after Ambu AuraGain complained of dysphonia in post-operative period. Sore throat was observed in 56% of patients after I-Gel and 48% of patients after Ambu AuraGain removal. Mild grade of Sore throat (1-3) was observed in 24% of the patients in Group I and 36% of the patients in Group A. Moderate grade of Sore throat (4-6) was observed in 32% of the patients in Group I and 12% of the patients in Group A. Thus, we observed that incidence of post-operative complications were higher with I-Gel as compared to Ambu AuraGain, which could be rendered to the comparatively difficult insertion of I-Gel, straighter and harder body, bulkier and non deflatable cuff. Also the need for more number of manipulations required during its insertion can also contribute to the same. Increased number of complications in both the groups can also be attributed to obese population under study. Our reason is supported by Shariffuddin

et al, who found post-operative complications with LMA protector in 48% of obese patients, rendering this high rate of complications to airway narrowing by increased hypolaryngeal adipose tissue deposition. Adding onto this, superficial fat deposition in neck of obese population can further compress airway externally. [45] Thus we conclude that in obese patients, all above factors lead to snugger fit of SAD, but removing LMA can cause increased chances of mucosal abrasions, blood stained LMA, dysphagia, dysphonia and sore throat post-operatively. In contrast to this, Prabha R et al, found comparable adverse effects between the obese and non-obese group. [31] Hence, we observed comparable incidence of post-operative complications and no device was found to be superior above the other. In the study by Chatterjee R et al , they found that blood staining on the cuff of I-Gel was greater than that of Ambu AuraGain but was not significant (p-value=0.72). Similarly they also found higher incidence of sore throat in I-Gel group (6.8 %) as compared to Ambu AuraGain group (2.3 %) , but the difference being statistically non-significant (p-value=0.3). They attributed the higher incidence of blood staining and sore throat in I-Gel group to its fixed and bulkier cuff. [38] However, contrary findings were noted in the study by Kim HJ et al, as they found that Ambu AuraGain group had more number of cases with blood stained cuff as compared to the I-Gel group. They attributed this difference to high cuff pressures of AuraGain leading to reduced pharyngeal mucosal perfusion causing airway complications. [29] Similarly, Lee HJ et al reported higher incidence of post-operative complications with I-Gel than AuraGain, but without statistical significance. [39] Thus both I-Gel and AuraGain can be associated with sore throat, blood staining of LMAs, other complications and none was found to be superior above the other.

There were certain limitations in our study. Double blinding was not possible for the type of device used due to obvious technical reasons. This could have led to bias. Moreover study was conducted on a smaller population. A large sample size might have resulted in better and significant result. We did not use fibreoptic bronchoscopy

to grade the glottis view for appropriate placement of the LMA but instead relied on other clinical criteria.

In the end we conclude that though both I-Gel and AuraGain were comparable in terms of oropharyngeal leak pressures, time and ease of insertion, manipulations required for adjustment, number of desaturation episodes and other post-operative complications, overall success of LMA in obese patients in laparoscopic surgeries was found to be inclining and trending towards a better performance of the Ambu AuraGain without a statistical significant difference. Hence we recommend more studies in obese patients to further validate the results of our study.

SUMMARY AND CONCLUSION

The study was conducted in the Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana after getting approval from the Institutional ethics committee. We compared oropharyngeal leak pressures during placement of I-Gel and Ambu AuraGain in obese patients.

Fifty ASA II-III adults with BMI ≥ 30 kg/m² scheduled for elective laparoscopic surgeries under general anaesthesia were studied in a prospective and randomised trial after obtaining a written informed consent. The patients were randomly allocated into two groups of 25 patients each using computer generated random numbers.

Group (I)- I-Gel LMA of appropriate size was inserted by the conventional technique with concavity facing mandible in a pen holding manner and inserting the device till it fits over the larynx (Brain's Technique).

Group (A)- Ambu AuraGain LMA of appropriate size was inserted by the standard recommended insertion technique.

Patients were assessed for OLP, time of insertion of LMA, number of attempts for successful LMA placement, ease of insertion, number of attempts for gastric tube placement, manipulations required to adjust LMA and post-operative complications if any. Results were analysed statistically.

The OLP before and after pneumoperitoneum of both the groups were comparable with p-value being 0.640 before pneumoperitoneum and 0.725 after pneumoperitoneum. We found no statistically significant difference in the OLP values of both the LMAs. Thus, both LMAs were comparable in terms of leak pressures in obese patients. We also observed that time of insertion, number of attempts required for insertion, ease of insertion of LMA, manipulations required for adjustment of LMA were comparable in both the groups.

Thus we conclude that I-Gel and Ambu AuraGain are both comparable and equally effective to secure airway in obese patients for laparoscopic surgeries. Both the LMAs demonstrated comparable high

leak pressures with good anatomical fit in obese population, thus reducing the risk of aspiration with no significant difference in time and ease of insertion, manipulations required to adjust LMA and post-operative complications. Hence both I-Gel and Ambu AuraGain can be safely used to secure airway in cases where high OLPs are required like obese patients and laparoscopic surgeries, in order to prevent risk of aspiration.

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KEYS TO MASTER CHART

%	Percentage
ASA	American Society of Anaesthesiologists
BMI	Body Mass Index
cm	Centimetres
cm H2O	Centimetres of water
CO2	Carbon dioxide
COPD	Chronic obstructive pulmonary disease
DBP	Diastolic Blood Pressure
DM	Diabetes Mellitus
EtCO2	End tidal carbon dioxide
F	Female
FB	Finger Breadth
HR	Heart Rate
HTN	Hypertension
kg	Kilograms
M	Male
min	Minutes
ml	millilitre
mm Hg	Millimetre of mercury
MPS	Mallampati Score
N/A	Not Applicable
NIBP	Non invasive Blood Pressure
OSA	Obstructive sleep apnoea
SBP	Systolic Blood Pressure
sec	seconds
SpO2	Oxygen saturation

S.No	MRD No.	Group	Type of LMA	Size of LMA	Date of surgery	Duration of surgery (in minutes)	Demographic data										Co-morbities				Criteria for successful placement		
							Age (in years)	Gender	ASA	Height (in cm)	Weight (in kg)	BMI	Neck circumference (in cm)	MPS	Thyromental distance (in cm)	Mouth opening	DM	HTN	COPD	OSA	Visible chest rise	Bilateral equal chest auscultation	Appearance of ETCO2 waveform
1	1428840	A	AuraGain	5	12-12-2022	90	45	F	II	160.02	90	35.1	39	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
2	1428026	I	I-Gel	4	13-12-2022	135	28	F	II	165.1	84	30.8	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
3	1298370	A	AuraGain	4	13-12-2022	75	65	F	III	160.02	84	32.8	38	III	> 6.5 cm	> 3 FB	NO	YES	NO	YES	YES	YES	YES
4	504921	A	AuraGain	5	15-12-2022	75	52	M	II	175.26	102	33.2	42	III	< 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
5	920910	A	AuraGain	3	15-12-2022	120	57	F	III	154.94	73	30.4	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
6	1432467	A	AuraGain	5	16-12-2022	150	58	M	II	172.72	90	30.2	40	IV	> 6.5 cm	2- 3 FB	NO	NO	NO	NO	YES	YES	YES
7	1432353	A	AuraGain	5	16-12-2022	120	40	M	III	177.8	140	44.3	42	III	6.5 cm	> 3 FB	YES	YES	NO	NO	YES	YES	YES
8	1012050	A	AuraGain	5	17-12-2022	90	45	M	III	170.18	96	33.1	41	III	> 6.5 cm	> 3 FB	YES	YES	NO	NO	YES	YES	YES
9	1433874	A	AuraGain	5	21-12-2022	90	60	F	II	165.1	82	30.1	38	III	> 6.5 cm	> 3 FB	YES	YES	NO	NO	YES	YES	YES
10	696253	I	I-Gel	5	22-12-2022	75	56	M	II	180.34	107	32.9	39	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
11	883291	A	AuraGain	5	23-12-2022	90	40	M	II	180.34	118	36.3	39	II	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
12	1438390	A	AuraGain	5	28-12-2022	150	27	F	II	160.02	87	34	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
13	1477290	A	AuraGain	4	11-03-2023	90	27	F	II	152.4	72	31	39	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
14	1482961	I	I-Gel	5	21-03-2023	120	47	M	II	185.42	115	33.4	40	III	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
15	772375	I	I-Gel	5	23-03-2023	120	48	M	II	170.18	91	31.4	39	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
16	1494850	A	AuraGain	4	11-04-2023	90	65	F	II	152.4	80	34.4	39	II	< 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
17	1496356	I	I-Gel	4	05-05-2023	90	50	M	II	165.1	84	30.8	38.5	II	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
18	1511919	A	AuraGain	4	06-05-2023	150	50	F	II	160.02	78	30.5	38	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
19	1510473	I	I-Gel	4	08-05-2023	120	34	F	II	162.56	80	30.3	39.5	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
20	1513200	I	I-Gel	4	09-05-2023	90	56	M	III	160.02	78	30.5	39	III	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
21	1514833	A	AuraGain	5	11-05-2023	90	52	F	III	165.1	120	45.4	42	IV	< 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
22	1514144	I	I-Gel	5	15-05-2023	120	65	M	III	170.18	128	44.2	42	III	6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
23	904888	I	I-Gel	4	24-05-2023	120	66	F	III	157.48	76	30.6	38	IV	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
24	1187543	I	I-Gel	5	03-07-2023	105	50	M	II	170.18	88	30.4	39	IV	> 6.5 cm	> 3 FB	YES	YES	NO	NO	YES	YES	YES
25	1547121	A	AuraGain	5	05-07-2023	60	59	M	II	170.18	95	32.8	41	III	< 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
26	1547271	I	I-Gel	5	06-07-2023	90	49	M	II	175.26	113	36.8	41.5	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
27	1548001	A	AuraGain	5	07-07-2023	90	67	M	II	165.1	85	31.2	39.5	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
28	150873	A	AuraGain	4	08-07-2023	105	22	F	II	157.48	78	31.5	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
29	1398466	A	AuraGain	4	10-07-2023	90	24	M	II	162.56	82	31	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
30	1181154	I	I-Gel	4	14-07-2023	135	48	F	II	152.4	70	30.2	38	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
31	1551568	A	AuraGain	4	17-07-2023	90	50	F	II	154.94	78	32.5	38	II	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
32	1553632	I	I-Gel	5	21-07-2023	120	67	M	III	175.26	127	41.3	42	II	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
33	1556227	I	I-Gel	3	21-07-2023	90	37	F	II	157.48	75	30.2	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
34	1557539	I	I-Gel	5	26-07-2023	120	50	M	II	170.18	100	34.5	39.5	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
35	1560492	I	I-Gel	5	28-07-2023	105	43	M	II	160.02	96	37.5	38.5	III	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
36	1562457	A	AuraGain	4	02-08-2023	150	51	F	II	154.94	80	33.3	38	II	> 6.5 cm	> 3 FB	YES	YES	NO	NO	YES	YES	YES
37	1559588	A	AuraGain	4	02-08-2023	90	83	M	III	177.8	95	30.1	39	IV	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
38	1565311	I	I-Gel	5	05-08-2023	90	38	M	III	162.56	96	41.3	40.5	III	< 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
39	1568039	I	I-Gel	4	10-08-2023	150	42	M	II	167.64	94	33.7	41.5	IV	< 6.5 cm	> 3 FB	YES	NO	NO	NO	YES	YES	YES
40	1568882	A	AuraGain	4	11-08-2023	150	50	M	II	167.64	86	30.6	38.5	I	> 6.5 cm	> 3 FB	YES	NO	NO	NO	YES	YES	YES
41	331335	A	AuraGain	4	11-08-2023	105	79	M	III	167.64	89	31.7	38.5	II	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
42	716853	I	I-Gel	4	17-08-2023	90	56	M	II	160.02	80	32.3	38.5	II	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
43	1575477	I	I-Gel	4	22-08-2023	150	27	F	II	162.56	100	37.8	39.5	II	< 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
44	1190623	I	I-Gel	5	23-08-2023	90	56	M	II	177.6	98	31	40.5	III	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
45	1575532	A	AuraGain	5	23-08-2023	135	64	M	III	172.72	98	32.9	39	III	> 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
46	1494892	I	I-Gel	5	23-08-2023	120	62	F	II	160.02	87	34	39.5	III	< 6.5 cm	> 3 FB	NO	YES	NO	NO	YES	YES	YES
47	1059916	A	AuraGain	4	26-08-2023	150	42	F	II	160.02	78	30.5	38.5	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
48	1463999	I	I-Gel	4	13-09-2023	120	60	F	III	157.48	76	30.6	38	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
49	1593029	I	I-Gel	5	21-09-2023	60	35	M	II	165.1	88	32.3	39	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES
50	1575373	I	I-Gel	4	27-09-2023	75	27	F	II	167.64	88	31.3	39	III	> 6.5 cm	> 3 FB	NO	NO	NO	NO	YES	YES	YES

S.No	Oropharyngeal Leak Pressures (cm of H2O)		Successful placement of LMA	Attempts	Insertion Time (in sec)	Change in size of device	Size of device changed	Change in type of device	Type of device changed	Manipulations done to adjust LMA	Type of manipulation	Attempts of gastric tube insertion	Ease of insertion of LMA	Heart rate(/min)						
	Before Pneumoperitoneum	After Pneumoperitoneum												Baseline	Induction	1 min	5 min	10 min	15 min	30 min
1	20	24	YES	1	20	NO	N/A	NO	N/A	NO	N/A	1	Easy	80	90	94	92	88	84	82
2	17	22	YES	1	17	NO	N/A	NO	N/A	NO	N/A	1	Easy	74	90	92	96	88	86	82
3	28	33	YES	1	22	NO	N/A	NO	N/A	NO	N/A	1	Moderate	65	72	80	58	60	68	64
4	18	24	YES	1	18	NO	N/A	NO	N/A	NO	N/A	1	Easy	84	78	90	82	86	94	92
5	17	21	YES	1	20	NO	N/A	NO	N/A	NO	N/A	1	Easy	70	88	96	90	86	84	82
6	17	27	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	92	88	98	86	90	78	94
7	24	28	YES	1	27	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	90	92	102	98	88	94	96
8	17	25	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt	1	Moderate	62	80	86	90	82	78	76
9	25	28	YES	1	25	NO	N/A	NO	N/A	NO	N/A	1	Easy	88	84	72	68	70	74	78
10	31	34	YES	1	21	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	74	70	64	78	82	80	76
11	31	35	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	90	92	100	88	84	100	102
12	23	26	YES	1	19	NO	N/A	NO	N/A	YES	Jaw thrust	1	Easy	92	96	82	90	87	78	82
13	22	25	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	90	82	98	78	74	82	88
14	20	28	YES	1	15	NO	N/A	NO	N/A	NO	N/A	1	Easy	82	90	98	92	98	94	98
15	26	31	YES	1	18	NO	N/A	NO	N/A	NO	N/A	1	Easy	88	94	102	98	78	74	72
16	28	31	YES	1	28	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	68	74	96	78	72	68	70
17	22	25	YES	1	18	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	82	90	94	78	74	72	68
18	23	N/A	YES	1	20	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	62	80	82	78	76	82	74
19	17	23	YES	1	18	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	64	78	62	68	70	66	74
20	21	25	YES	1	20	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	3	Moderate	62	80	64	58	62	68	70
21	28	33	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	76	100	91	90	90	87	95
22	27	30	YES	2	29	NO	N/A	YES	I-Gel (size-5)	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	82	92	89	84	89	88	88
23	23	24	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	64	68	74	65	63	64	68
24	21	24	YES	1	18	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	62	70	72	68	74	76	80
25	23	28	YES	1	20	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	68	74	72	68	74	66	70
26	23	27	YES	1	26	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Moderate	102	109	108	106	108	106	107
27	20	23	YES	1	20	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	70	78	82	86	74	68	66
28	18	23	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	86	95	98	90	84	82	88
29	18	22	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	82	84	78	74	80	85	70
30	17	22	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	98	104	105	104	109	104	105
31	19	24	YES	1	19	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	74	80	82	78	68	72	74
32	25	29	YES	1	23	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	2	Difficult	84	86	70	88	76	82	88
33	21	25	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Chin lift	1	Moderate	94	102	104	84	90	86	84
34	18	22	YES	1	20	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Moderate	62	84	76	74	70	78	80
35	22	27	YES	1	18	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	76	82	88	72	68	78	80
36	26	30	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Moderate	78	84	96	76	80	70	68
37	26	27	YES	2	22	NO	N/A	YES	AuraGain (size-4)	YES	Head tilt,Chin lift	2	Difficult	84	90	96	82	88	78	84
38	25	34	YES	1	28	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	62	74	78	68	54	53	55
39	32	40	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	82	88	92	78	72	76	80
40	17	27	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Moderate	96	102	92	88	82	94	78
41	20	24	YES	1	20	NO	N/A	NO	N/A	NO	N/A	1	Easy	76	90	96	86	82	84	78
42	18	23	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	77	92	90	84	88	76	74
43	23	27	YES	1	25	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	62	72	84	68	64	72	62
44	23	25	YES	1	25	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	86	92	102	96	88	78	82
45	18	21	YES	1	22	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	62	76	76	59	62	68	66
46	22	25	YES	1	28	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	80	94	90	74	76	84	72
47	18	24	YES	1	21	NO	N/A	NO	N/A	YES	Head tilt,Chin lift	1	Moderate	92	88	96	72	104	84	78
48	24	29	YES	1	28	NO	N/A	NO	N/A	YES	Head tilt, Chin lift, Jaw thrust	1	Difficult	84	90	94	88	66	64	72
49	17	23	YES	1	22	NO	N/A	YES	I-Gel (size-5)	YES	Head tilt,Chin lift	1	Moderate	64	80	84	66	62	68	72
50	24	29	YES	1	24	NO	N/A	NO	N/A	YES	Head tilt, Jaw thrust	1	Moderate	78	82	90	72	68	74	78

S.No	Haemodynamic Parameters																														
	SBP(mm Hg)							DBP(mm Hg)							SpO2(%)							Expired Tidal Volume(ml)							Peak Pressu		
	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	Baseline	Induction	1 min
1	150	166	170	158	146	142	144	90	98	100	88	86	82	78	100	100	100	100	100	100	100	550	520	510	560	560	540	530	12	19	22
2	110	86	90	100	102	117	114	60	58	60	54	60	74	70	96	100	100	100	100	100	100	480	490	510	465	470	462	458	14	19	23
3	130	120	134	128	102	138	132	90	86	92	88	68	96	90	98	100	100	99	98	99	99	480	475	440	490	510	465	485	20	28	29
4	146	150	158	144	136	148	152	78	82	90	76	72	82	94	96	100	98	96	96	96	96	580	550	450	480	510	475	460	14	22	24
5	110	108	92	116	117	126	112	70	68	60	90	82	88	74	98	100	100	100	100	100	100	412	420	460	490	498	487	470	15	17	17
6	120	130	144	158	142	148	136	78	84	90	96	88	92	82	97	100	98	97	96	96	96	580	550	500	560	605	565	550	16	17	22
7	140	120	110	102	128	132	144	90	80	78	74	84	88	92	97	99	95	93	89	92	92	560	550	535	540	530	535	530	22	24	28
8	154	158	162	160	156	148	154	100	102	104	100	100	96	98	97	99	97	96	96	96	96	590	550	510	490	485	495	505	17	19	25
9	140	136	126	135	122	136	140	86	80	72	82	70	74	78	100	98	98	98	98	97	98	420	464	480	472	500	412	490	20	24	24
10	140	144	128	110	168	162	151	90	100	82	74	110	104	97	98	98	97	97	98	97	97	650	610	540	515	482	497	503	27	29	31
11	128	114	99	130	135	138	136	80	78	60	90	92	96	94	98	100	100	97	96	97	97	622	550	520	518	510	512	530	20	22	30
12	130	128	104	99	126	133	135	90	82	70	66	82	98	98	98	100	100	98	97	97	98	480	500	412	450	464	468	420	19	21	23
13	120	122	140	138	142	130	128	80	80	86	82	90	78	76	100	100	100	98	97	96	96	500	490	480	475	425	464	430	19	20	22
14	118	122	130	158	146	144	130	70	76	80	98	91	88	76	94	98	98	97	95	94	93	650	625	530	525	540	535	520	17	17	18
15	120	118	130	124	115	124	122	90	84	92	88	80	84	80	96	100	100	98	96	96	96	600	580	525	480	520	515	524	20	22	24
16	150	158	136	118	130	126	134	78	82	70	66	68	66	70	97	100	100	98	97	97	97	460	504	484	488	460	494	470	18	20	22
17	130	140	118	109	107	111	103	90	96	82	76	73	76	74	98	100	99	99	98	98	98	500	520	480	483	462	475	506	15	16	16
18	106	120	130	110	132	128	122	64	78	88	66	90	84	76	98	100	94	99	100	100	100	480	450	110	450	475	420	422	20	20	28
19	116	108	98	126	133	122	127	82	78	64	84	88	77	89	98	100	100	100	100	100	100	405	430	452	442	427	456	460	15	15	17
20	118	129	122	144	138	132	113	76	94	90	99	86	84	72	98	100	97	97	95	89	94	600	625	520	525	490	475	480	17	20	23
21	130	138	140	141	140	138	138	90	85	80	68	85	86	79	97	97	98	96	95	95	95	492	500	510	495	509	508	516	30	30	31
22	138	128	167	147	148	153	127	82	78	100	91	91	94	82	98	100	100	100	100	100	100	610	602	532	531	534	530	528	26	26	28
23	162	148	155	137	130	117	136	94	91	92	90	82	75	85	98	100	100	99	100	100	99	420	460	464	482	492	490	479	13	15	20
24	134	141	110	128	114	124	134	87	85	70	80	72	78	86	96	98	97	98	94	95	97	480	420	418	403	450	420	418	13	13	15
25	130	141	153	149	130	159	144	80	86	100	99	84	96	96	97	99	99	99	99	99	99	580	565	540	545	517	530	535	15	16	17
26	128	113	119	129	147	136	135	84	69	64	88	107	97	91	97	99	99	98	99	99	98	600	510	480	490	514	485	507	12	17	19
27	140	130	100	133	149	114	132	90	82	47	81	93	59	80	98	100	100	100	99	98	98	510	440	474	466	475	435	454	10	16	21
28	110	120	96	126	105	122	118	70	92	62	88	74	85	76	96	100	100	100	100	100	100	500	520	518	540	550	480	495	10	12	17
29	127	119	105	109	106	114	110	90	65	61	62	57	69	62	98	100	100	100	100	100	100	520	490	504	475	510	460	478	10	14	14
30	136	145	115	108	150	148	154	93	97	77	69	98	89	94	98	100	100	100	98	98	98	428	406	416	414	440	435	422	5	14	14
31	130	128	112	135	142	138	126	80	72	80	86	90	84	70	98	100	100	100	98	98	98	520	480	415	470	424	474	440	8	10	16
32	110	108	96	97	99	108	102	70	72	71	74	63	73	64	97	100	99	98	98	98	98	520	490	485	478	503	495	523	9	12	20
33	110	105	98	121	112	108	116	80	80	74	81	64	62	68	98	100	100	100	100	100	100	550	425	430	419	435	420	444	4	12	15
34	120	119	100	108	106	128	135	70	79	58	71	70	74	81	96	100	100	100	100	100	100	612	550	476	485	450	424	460	10	12	15
35	130	125	100	132	128	124	112	70	65	58	74	64	55	52	98	100	100	98	97	97	97	350	400	404	415	390	385	410	7	12	18
36	160	136	102	144	148	132	154	100	80	63	81	82	78	92	99	100	100	98	97	97	97	615	520	505	480	485	420	460	5	12	18
37	160	138	119	124	140	128	136	100	86	75	67	74	73	80	98	100	100	99	98	98	98	520	550	496	488	413	522	526	12	12	18
38	130	159	146	133	128	122	116	90	98	88	83	79	72	69	95	100	98	96	94	92	92	420	510	506	473	500	497	499	12	17	23
39	130	116	106	120	118	128	108	80	72	62	74	70	81	60	98	98	100	100	97	96	96	550	615	580	520	516	524	572	8	12	23
40	166	154	125	125	167	152	138	104	92	81	85	102	89	84	97	100	100	99	99	100	99	560	440	439	416	420	450	470	8	12	13
41	130	122	102	121	134	137	128	72	69	64	74	86	91	79	97	100	100	100	98	98	97	510	520	535	510	490	484	505	11	12	17
42	110	96	102	123	143	135	129	70	69	72	78	89	74	77	98	100	98	98	97	98	97	440	474	490	504	496	480	475	10	11	18
43	130	132	93	110	128	136	132	80	76	49	64	75	94	90	98	100	98	98	97	98	97	402	410	386	401	461	425	432	8	10	15
44	130	104	110	132	151	145	136	90	76	79	92	109	84	82	97	100	100	97	96	96	96	490	510	520	485	494	510	504	12	15	20
45	120	94	92	123	118	108	121	80	58	64	64	67	62	69	96	100	99	95	94	95	95	466	504	520	512	484	490	515	10	12	14
46	130	126	141	145	137	149	132	80	84	92	87	91	96	87	96	100	97	95	94	95	95	490	485	420	417	404	462	414	14	14	20
47	120	128	100	112	142	134	127	70	75	56	65	94	79	71	99	99	99	99	98	97	97	484	502	524	490	472	508	460	10	12	16
48	110	107	92	105	106	115	107	77	60	52	59	62	64	59	98	100	100	100	100	100	100	460	500	510	494	462	517	490	12	14	18
49	120	137	108	128	129	118	142	80	90	72	74	82	70	90	98	100	100	100	98	98	98	545	600	520	490	467	422	504	8	12	14
50	110	90	99	107	124	131	124	70	63	67	71	76	79	72	97	100	100	98	97	96	96	480	520	510	494	468	504	480	10	12	19

S.No	Respiratory Parameters																		Complications					
	res(cm of H2O)				Plateau Pressures(cm of H2O)							EtCO2(mm Hg)							Desaturation	No. of	Blood	Dysphagia	Dyphonia	Sore throat
	5 min	10 min	15 min	30 min	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	Baseline	Induction	1 min	5 min	10 min	15 min	30 min	episodes(SpO2<90%)	desaturation	staining			grade
1	24	23	25	24	10	17	20	22	21	23	22	36	36	35	33	32	33	32	NO	N/A	NO	NO	NO	0
2	25	25	26	23	10	18	21	25	25	23	21	28	32	35	34	35	35	35	NO	N/A	NO	NO	NO	0
3	33	32	34	33	18	26	27	30	30	32	31	28	30	32	35	33	32	34	NO	N/A	NO	NO	NO	3
4	26	24	24	24	12	20	22	24	22	22	22	28	32	33	32	35	33	33	NO	N/A	NO	NO	NO	0
5	18	23	22	23	17	17	18	20	25	25	25	28	30	30	33	35	33	32	NO	N/A	NO	NO	NO	0
6	24	27	27	24	14	16	20	21	25	25	22	30	30	35	34	34	35	35	NO	N/A	NO	NO	NO	2
7	33	32	33	32	20	22	24	30	30	31	30	30	32	33	33	32	33	33	YES	1	NO	NO	NO	4
8	27	27	26	27	15	18	22	25	25	24	25	30	32	36	36	35	36	36	NO	N/A	NO	NO	NO	2
9	23	28	27	28	18	22	22	20	27	26	25	30	33	36	37	36	34	34	NO	N/A	NO	NO	NO	1
10	32	35	37	37	25	28	28	31	31	34	35	28	28	30	32	34	36	35	NO	N/A	NO	NO	NO	4
11	31	35	33	31	17	20	28	29	33	31	29	30	32	31	35	36	38	35	NO	N/A	NO	NO	NO	0
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13	26	25	26	25	17	17	18	22	21	23	22	30	30	36	35	32	32	33	NO	N/A	NO	NO	NO	0
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15	26	25	25	26	18	19	22	23	23	20	21	32	32	34	35	37	35	38	NO	N/A	NO	NO	NO	1
16	22	24	24	22	16	17	18	18	20	21	20	28	30	32	30	36	34	34	NO	N/A	NO	NO	NO	0
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20	23	25	24	24	15	18	21	22	23	22	23	30	32	30	35	35	36	35	YES	1	NO	NO	NO	0
21	32	33	34	35	21	25	28	23	23	25	25	30	33	32	33	32	33	33	NO	N/A	NO	YES	NO	4
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24	20	22	23	22	12	12	13	17	21	21	20	29	30	32	31	34	33	34	NO	N/A	NO	NO	NO	0
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26	24	27	29	33	10	14	15	18	20	24	28	30	33	35	36	38	36	34	NO	N/A	NO	NO	NO	2
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39	25	30	32	31	5	10	18	22	28	29	28	28	29	30	32	34	33	35	NO	N/A	NO	NO	NO	0
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43	24	23	24	24	5	8	15	22	23	22	23	30	32	35	36	36	37	36	NO	N/A	NO	NO	NO	0
44	21	25	26	23	10	12	18	18	23	24	21	28	30	32	33	35	36	35	NO	N/A	NO	YES	NO	3
45	20	22	21	21	8	10	14	18	20	18	19	26	28	30	31	33	32	33	NO	N/A	NO	NO	NO	0
46	27	27	27	24	12	13	19	25	26	25	22	26	28	30	31	34	34	33	NO	N/A	NO	NO	YES	4
47	18	22	24	25	8	12	14	15	21	22	23	26	28	28	32	34	35	33	NO	N/A	NO	NO	NO	0
48	22	25	26	24	10	12	15	19	23	24	22	28	30	32	34	37	36	34	NO	N/A	NO	NO	NO	4
49	17	23	22	20	5	10	12	15	21	19	18	28	30	32	29	31	30	30	NO	N/A	NO	NO	NO	0
50	21	24	23	24	8	10	17	20	22	21	21	26	28	31	30	34	35	33	NO	N/A	NO	YES	NO	3

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Subject:: **Approval of Plan of Thesis.**

This is to inform you that the Faculty of Medical Sciences in its meeting held on 25.09.2023 has approved the plan of thesis of **Sameera Kohli**, a student of your college for **MD Anaesthesiology** along with the names of Supervisor/Co-Supervisor as under:-

Topic Plan of Thesis
Comparative evaluation of oropharyngeal leak pressures during placement of i-gel and ambu auragain in obese patients .

Supervisor	Co-Supervisor:-
Dr. Kamakshi Garg	Dr. M. Rupinder Singh
Professor	Professor
Dept. of Anaesthesiology	Dept. of Anaesthesiology

The student may submit the thesis in triplicate alongwith the plan in triplicate also, to the Controller of Examinations, BFUHS, Faridkot, at least six months before the commencement of theory examination, if he/she is otherwise eligible to take the examination. He /She may be directed to attach a photocopy of this letter with the forwarding letter while submitting thesis in the University along with the letter of approval of University for change of supervisor/Co-Supervisor, change of topic, if any.

Controller of Examinations

Note :

1. *If any discrepancy found regarding topic of thesis or Supervisor/Co-Supervisor, inform undersigned within one month after issue of this letter.*

COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS

THESIS PROPOSAL

FOR APPROVAL OF SUBJECT OF THESIS TO BE SUBMITTED IN

PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE DEGREE OF

MD

In

ANAESTHESIOLOGY

OF THE

BABA FARID UNIVERSITY OF HEALTH SCIENCES

FARIDKOT

AUGUST, 2022

DR SAMEERA KOHLI

DEPARTMENT OF ANAESTHESIOLOGY
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LUDHIANA

ABSTRACT OF PLAN OF THESIS

Title	COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS
For the degree of	MD Anaesthesia
Name of the candidate	Dr. Sameera Kohli
Supervisor	Dr. Kamakshi Garg, Professor, Department of Anaesthesia, DMCH, Ludhiana
Co-Supervisor	Dr. M. Rupinder Singh, Professor, Department of Anaesthesia, DMCH, Ludhiana
Institution	Dayanand Medical College and Hospital, Ludhiana
University	Baba Farid University of Health Sciences, Faridkot

Introduction- Supraglottic airway devices (SADs) have been used for routine airway management and maintenance during anesthesia in patients without increased risks for aspiration of gastric contents. SADs offer an alternative airway to traditional tracheal intubation with potential benefits, including ease of fitness and less airway disturbance.Morbidly obese patients are at risk of difficult mask ventilation as well as intubation. . Airway of these patients is a major concern for an anesthesiologist while providing general anesthesia. SADs act as a useful alternative in obese patients.

Aims and objectives- To compare oropharyngeal leak pressures as a measure of successful placement of I-Gel and Ambu AuraGain LMA in obese patients undergoing laparoscopic surgeries.

Materials and methods- A randomized control comparative study will be conducted on 50 obese patients undergoing laparoscopic surgeries. In group A, Ambu Auragain will be used and in group I, I-Gel LMA will be inserted and these will be compared with respect to oropharyngeal leak pressures.

Clinical significance- Comparison of two Supraglottic Airway Devices, namely, Igel and Ambu Aura Gain, with respect to, oropharyngeal leak, and to find out which one consumes less time with optimal haemodynamics and minimum drop in saturation in obese patients.

Keywords- Supraglottic Airway Devices, Laparoscopic surgeries, Obesity, Oropharyngeal leak pressures.

(Signature) Candidate

(Signature) Co-supervisor

(Signature) Supervisor

(Signature) Principal

CERTIFICATE OF FACILITIES AVAILABLE

This is to certify that the facilities for work on the subject of thesis titled **"COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS"** exist in the Department of Anaesthesia at Dayanand Medical College and Hospital, Ludhiana and will be provided to the candidate. We will see that the data being included in the thesis are genuine and is collected by the candidate herself under our supervision and guidance.

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APPROVAL PROFORMA
BY
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Approved: Yes / ~~No~~

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4.	DATE OF ADMISSION OF COURSE	05 March,2022
5.	TITLE OF THE TOPIC	COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS

6. BRIEF RESUME OF THE INTENDED WORK

6.1 NEED FOR THE STUDY

Obesity accounts for 11% of the world's total population, according to WHO. An anaesthesiologist will encounter obese patients quite often. Airway of an obese individual is a major concern for an anesthesiologist while providing general anesthesia or securing the airway in the intensive care unit.[1]

Obesity is a known risk factor, associated with many complications in anaesthesia, including difficult airway. Obesity leads to physiological as well as anatomical difficult airway. Endotracheal intubation is usually done in most surgeries but incidence of difficult intubation in an obese patient is much higher than normal weight patients.[2,3] Obese individuals have a limited neck movement due to restriction of atlanto-axial joint and cervical spine by upper thoracic and lower cervical fat pads and they usually have short thick neck. The excessive tissue fold in mouth may be missed during routine preanaesthetic check-up. They also have suprasternal, presternal and posterior cervical fat and a very thick submental fat pad.[4] All these factors contribute to a difficulty in laryngoscopy and tracheal intubation.

Supraglottic Airway Devices [SADs] are used in difficult airway management, where they can be used for oxygenation and also as conduits for insertion of tracheal tubes in the scenarios of difficult or failed intubation. These also act as a rescue device in the cases of difficult oxygenation with the facemask.[5]

With new and improved versions of these devices, they can be used in some borderline indications, such as laparoscopic surgeries in the obese patients. SADs can be used alone to maintain the airway during short surgical procedures or it can act as a conduit for passage of endotracheal tube during major surgical procedures or in the intensive care. Many

studies have shown that SADs can be used in obese patients without any fear of airway related complications.[6] Nowadays, many SADs can be used as valuable equipment for morbidly obese patients and they are considered standard tool for airway management in clinical practices.[5]
Over a period of time, new modifications were done in classic LMA model to incorporate second tube placement, lateral to the airway channel to facilitate passage of nasogastric tube, separate respiratory & oesophageal pathways & permit escape of gastric contents to reduce risk of gastric insufflation, regurgitation & pulmonary aspiration. Various such models are: LMA ProSeal, LMA supreme, Aura Gain, I-Gel etc. [7] First generation LMAs can lead to higher incidences of pulmonary aspiration in obese patients. Second generation LMAs offer better access & functional separation of the respiratory & digestive passages, high leakage pressure, optimal fit of the airway device & dual gastric ports.

A new variant of LMA – " I-gel " (Intersurgical Ltd, Wokingham, Berkshire) developed in 2007 [6,8] , made of thermoplastic elastomer, which is soft, transparent, gel like & designed to anatomically fit the perilaryngeal & hypolaryngeal structures, without an inflatable cuff.[9]

Ambu Aura Gain (Ambu, Ballerup, Denmark) is a novel cuffed SGA introduced in 2015, which has a preformed curve & also a built in gastric port. [4] It has the capability of working as a conduct for intubation. The airway tube of Aura Gain is broader, thereby accommodating comparatively bigger Endotracheal Tube (ETT).[10,11]

In this randomised study, we would like to compare two Supraglottic Airway Devices, namely, Igel and Ambu Aura Gain, with respect to, oropharyngeal leak, and to find out which one consumes less time with optimal haemodynamics and minimum drop in saturation in obese patients.

6.2 REVIEW OF LITERATURE

Obesity is usually associated with difficult airway, difficult bag mask ventilation, difficult laryngoscopy, difficult endotracheal intubation and an added risk of aspiration.[12]

Obese patients have short thick neck, restricted neck movements and more peri-laryngeal soft tissue therefore it is difficult to get the oral, pharyngeal and laryngeal inlet in line for endotracheal intubation. Apart from the anatomically difficult airway, they also have a physiologically difficult airway which includes reduced functional residual capacity, increased oxygen consumption, reduced lung volumes higher minute ventilation, reduced chest wall compliance and increased airway resistance.[12-14] This predisposes them to multiple episodes of desaturation during airway management especially during laryngoscopy and endotracheal intubation.[12]

They usually have concomitant co-morbidities like diabetes mellitus, hypertension, obstructive sleep apnoea, chronic obstructive pulmonary disease, gastro-oesophageal reflux disease, etc. which further predisposes them to physiologically and anatomically difficult airway.

Endotracheal intubation is the preferred choice for securing the airway and for mechanical ventilation during general anaesthesia in obese patients.[14]

Furthermore the difficult laryngoscopy and intubation in an obese patientresults in increased haemodynamic stress response. [13,15] In addition there have been reports of higher incidence of hoarseness, sore throat, dysphagia etc due to multiple attempts at endotracheal intubation.[13,15]

As an alternative to endotracheal intubation, second generation supraglottic airway devices (SADs) has proved beneficial in obese patients because of the easy insertion coupled with higher rates of successful insertion at first attempt.[13,16,17]

Multiple investigators have compared endotracheal intubation with SAD on parameters like leak pressure, ease of insertion and urgency to secure

airway. They concluded that SAD can be used as an alternative to endotracheal intubation.[13,16,18,19]

Zoremba M et al, recruited 162 patients posted for short to medium duration surgeries of 40-120 minutes and compared intubation and Proseal LMA in moderately obese adults. They included the data of 134 patients after accounting for dropouts and aimed to evaluate the influence of airway management i.e intubation versus LMA on postoperative lung volumes and arterial oxygen saturation in early post-operative period. They concluded that the use of an LMA during minor peripheral surgery confers advantages for moderately obese adults in terms of early recovery of post-operative lung functions and may be considered as an alternative to endotracheal intubation for moderately obese patients undergoing short surgeries.[14,16]

Cochrane systematic review comparing studies on use of Proseal LMA and Endotracheal tube (ETT) in obese patients concluded that, though PLMA takes more time to insert than ETT and a failure rate of 3-5% can be anticipated in obese patients, but once properly fitted it provides equally good ventilation as endotracheal intubation. They found significant improvement in oxygenation during and after the surgery and reduced post-operative complications like coughing, sore throat, hoarseness, etc with the use of PLMA.[13]

Uppal V et al, compared I-gel® with cuffed tracheal tube during pressure controlled ventilation (PCV) in 20 patients. They found that there was no significant difference in the leak fractions between the two groups at 15-20 cm H_2O. There was no evidence of gastric insufflations with I-ge®l at any of the pressures used during PCV. Hence I-gel® can be used as a reasonable alternative to tracheal tube during PCV with moderate airway pressures.[19]

Lai CJ et al, compared I-gel® with ETT in 40 non-obese patients undergoing laproscopic pneumoperitoneum surgeries. They evaluated the respiratory parameters in supine and trendlenberg position and found no difference in the leak fraction between I-gel® and ETT group (6.20% vs 6.38% respectively), (P=0.883). They concluded that I-gel® provides a suitable alternative to ETT when using LPT positioning. The I-gel® group produced similar leak fractions, leak volumes and airway pressure to the ETT group. In addition, the I-gel® group had significantly lower resistance and higher compliance compared with the ETT group. They proposed that the difference can be because of the lower internal diameter of I-gel® as compared to ETT.[18]

SAD can be used to secure airway in elective as well as emergency situations and are proved beneficial even when dealing with obese patients.

Murphy C et al in a review stated that airway management and oxygenation in obese patients is challenging. These challenges in oxygenation and ventilation may persist throughout the perioperative period. They suggested that newer generation double lumen supraglottic airway devices provide higher leak pressures and may be considered safe in obese patients. They can also provide a conduit for bronchoscopic intubation. Although second generation SAD are safer in obese patients but there are risks of aspiration hence caution should be exercised while using these devices in morbidly obese individuals.[12]

All the different types of LMA have been studied and compared so far. Second generation LMA have a gastric outlet to prevent gastric insufflation. Various studies have shown advantages of I-gel® over other LMA. I-gel® has a non-inflatable gel like cuff made up of thermoelastic material and a buccal stabilizer to prevent malpositioning. It fits with the patient's perilaryngeal anatomy and provides a reliable seal.[15,18,20] It is easier to insert and has high success rates of insertion at first attempt. It can be used as a rescue device to secure airway in emergency conditions.

The size of I-gel® to be inserted is based on manufacturer's guidelines (30-60 kg - size 3, 50-90 kg - size 4, >90 kg - size 5).[15-17,21]

In a randomised trial on comparative evaluation of ProSeal LMA (P), I-gel® (I) and Supreme LMA (S) in 84 adult patients undergoing elective surgery by Singh A et al, showed that the OLP was more with P than I and S but I-gel® was easier to insert and least time consuming also. The OLP of I-gel® increased towards the end of the surgery due to its thermoelastic hood which expands due to body temperature.[22] This high OLP is advantageous for our study as it would provide better seal and hence lesser chances of oesophageal reflux.

There are many methods to check OLP. In a study by Keller C et al, four methods were suggested for assessing airway sealing pressure with LMA in adults. Test (1) audible noise: involved detection of an audible noise by listening over the mouth. Test (2) oral capnography: involved placing a carbon di-oxide sampling line 5cm inside the mouth alongside the LMA tube and noting when CO_2 was first seen above baseline on the monitor screen. Test (3) manometric stability: involved observation of an anaeroid manometer dial as the pressure from the breathing system increased, and noting the airway pressure at which the leak was in equilibrium with fresh gas flow. Test (4) auscultation: involved detection of an audible noise using a stethoscope placed just lateral to thyroid cartilage. They concluded that all of these tests for assessing OLP are excellent.[23]

A study by Weber U et al compared I-gel® and LMA-Unique in 50 patients in terms of leak pressure, ease of insertion, time and number of attempts of insertion in mild to moderately obese patients posted for elective short-term surgeries. They observed slightly lower scores for difficulty of insertion with LMA-Unique and statistically significant shorter insertion time with I-gel®. They observed that I-gel® can be used with higher ventilatory pressures than LMA-Unique. Hence I-gel is a safe and effective

alternative supraglottic airway device in patients with mild to moderate obesity with mouth opening < 4cm.[15]

Uppal V et al, studied randomized crossover comparison between the performance of I-gel® and LMA-Unique in 39 anaesthetized, paralysed non-obese adults and found that there were no significant differences between the airway leak pressures and success rate of first time insertion of the two devices. The number of manipulations required after insertion to achieve a definitive airway was similar in both the groups. They concluded that I-gel® is a reasonable alternative to LMA-U for volume controlled ventilation during anaesthesia, also it has a lower insertion time.[24]

LMA can also be inserted without the use of muscle relaxant but in obese patients muscle relaxant helps in decreasing the tone of laryngeal and pharyngeal muscles and aid in easy and less traumatic insertion of the device.[25]

In a study by Krishnappa S. et al, to assess whether loss of motor response to jaw thrust can be a reliable clinical indicator of anaesthetic depth for LMA insertion. They used propofol in titrated doses till the loss of motor response to jaw thrust in one group and fixed dose in the other. They found that loss of motor response to jaw thrust is reliable and favourable indicator for insertion of LMA classic.[26]

Prabha R. et al compared I-gel® for general anaesthesia in obese and non-obese patients. A total of 32 patients were studied and results showed a higher mean OLP for obese patients than non-obese. The use of muscle relaxants decreased the tone of laryngeal and pharyngeal muscles and reduced the OLP of SAD. Excess parilaryngeal tissue in obese patients may lead to better seal between the cuff of I-gel® and laryngeal inlet. They concluded that I-gel® is as effective in obese patients as in non-obese patients when used for securing the airway for surgical procedures.[24]

Nasseri K. et al studied effect of low dose atracurium on LMA insertion They found that jaw relaxation and ease of LMA insertion in the study group is significantly better than the control group (without the use of relaxant). Average time needed for insertion was also significantly lower in the study group. Haemodynamic response was similar in both groups and post-operative complications like sore throat were more in control group. They concluded that using low dose atracurium decreases the time taken for LMA insertion, it increases the jaw relaxation and facilitates the placement of LMA.[25]

6.3 AIMS AND OBJECTIVES OF THE STUDY

To compare oropharyngeal leak pressures as a measure of successful placement of I-Gel and Ambu AuraGain LMA in obese patients undergoing laparoscopic surgeries.

7. MATERIALS AND METHODS

7.1 SOURCE OF DATA

The study will be conducted in Department of Anaesthesiology, Dayanand Medical College and Hospital, Ludhiana, after approval from the Institutional Ethics Committee. A written informed consent will be obtained from all patients, of either gender, selected for study.

7.2 METHOD OF COLLECTION OF DATA

Inclusion Criteria

- Age 18 Yrs-70 Yrs
- BMI>30 kg/m^2
- Fulfilling the criteria of ASA I, II & III

Exclusion Criteria

- Laparoscopic converted to open surgery
- Refusal to participate
- Infections or Pathology of airway.
- Limited mouth opening(<24 mm)
- Patients with history of hiatus hernia
- Pregnancy, reduced lung compliances
- Edentulous
- Need for conversion from LMA to ETT.

Group Allocation-

A written informed consent will be obtained from all the patients. Patients will be randomly divided into 2 groups of 25 patients each. Randomisation will be done by computer generated random numbers.

Group (I)- I-Gel LMA of appropriate size will be inserted by the conventional technique with concavity facing mandible in a pen holding manner and inserting the device till it fits over the larynx (Brain's Technique).

Group (A)- Ambu AuraGain LMA of appropriate size will be inserted by the standard recommended insertion technique.

All patients will be subjected to routine pre-operative assessment and standard fasting protocols.

In the operating room (OR), all patients will be positioned in Ramp position. Monitors will be attached in the form of pulse oximeter, non invasive blood pressure (NIBP), end tidal CO_2 ($EtCO_2$), 5 lead electrocardiography (ECG). After positioning and settling of patient on OR table, baseline value will be recorded from the mean of three values. Intravenous access will be secured and intravenous injections of midazolam 0.05 mg/kg and metoclopramide 10 mg or ondansetron 4 mg will be administered. After pre-oxygenating the patient with 100% oxygen for 3-5 minutes with a tight fitting appropriate size anatomical face mask, anaesthesia will be induced with intravenous injection of fentanyl 2mcg/kg and 1% propofol 2-2.5 mg/kg titrated to loss of verbal response. Neuromuscular blockade will be achieved by intravenous injection of atracurium 0.5 mg/kg.

Ambu AuraGain LMA will be fully deflated and both SGAs will be fully lubricated with water soluble jelly prior to insertion. The size of 3/4/5 of either device will be selected according to the weight of the patient.

After achieving adequate depth of anaesthesia and muscle relaxation,the insertion of randomly selected LMA(I-Gel/Ambu AuraGain) will be performed by a single anaesthesiologist with >3 years of experience in using the SGA devices. The standard recommended insertion technique will be tried for the first attempt. In case of resistance, adjusting maneuvers such as lateral rotation of cuff, jaw lift, head and neck

extension will be applied and noted. [6] An independent observer will note the time of insertion of LMA. [16]

After insertion, the cuff of Ambu Auragain shall be inflated with air to attain a cuff pressure of 60 cm of water as measured by hand held cuff pressure manometer.

A nasogastric tube of appropriate size will be passed through the gastric tube channel in all the cases.

The lungs will be mechanically ventilated using volume controlled ventilation delivered by an anaesthesia work station (Drager Fabius Plus/Primus) to deliver a tidal volume of 8ml/kg, respiratory rate to maintain $EtCO_2$ between 30 and 40 mmHg, inspiratory and expiratory ratio of 1:2 and a peak end-expiratory pressure of 5 cm of water.

Initial assessment of ventilation is performed by observing the square wave capnograph and chest rise.

The total fresh gas flow will be maintained at 1.5 L/min. Anaesthesia will be maintained by desflurane or sevoflurane in 50:50 Oxygen and nitrous oxide. Additional fentanyl 1mcg/kg i.v. will be given when clinically needed during anaesthesia. Any need for conversion for LMA to ETT shall be considered as failure of study and the case shall be excluded from the study. Oropharyngeal pressures shall be measured before and after pneumoperitonium.

At the end of the procedure neuromuscular blockade will be reversed using intravenous injections of neostigmine 0.04 mg/kg and glycopyrrolate 0.005 mg/kg and LMA will be removed after confirming the return of spontaneous and normal pattern of ventilation with sustained head lift for atleast 5 seconds. Sustained hand-grip, leg-lift or eye opening have been demonstrated to have a low sensitivity in predicting recovery of

neuromuscular function. Patients will then be shifted to post-anaesthesia care unit for observation.[27]

Observations:

PRIMARY OUTCOME-

To compare oropharyngeal leak pressures of I-Gel and Ambu AuraGain- To perform the OLP, the fresh gas flow will be adjusted to 3L/min, and the adjustable pressure limiting valve of the circle system will be completely closed. With no peak end expiratory pressure the minimum airway pressure will be measured at which audible gas leak starts to occur as heard using a stethoscope placed just lateral to the thyroid cartilage. Airway pressures will not be allowed to exceed 40cmH_2O. [28]

Successful placement at first attempt **-** The LMA is deemed to be correctly placed if there is "successful ventilation", which is confirmed by: B/L symmetrical chest wall rise, auscultation of breathe sounds, square wave capnographic curves and no oropharyngeal leak.

SECONDARY OUTCOMES-

1. **Time of insertion-**The insertion time will be defined as the time from picking up the device until confirmation of successful ventilation. Maximum time allowed for each attempt will be 60 seconds.
2. **No. of attempts of insertion of device and failed attempt**
    - Attempt is defined as insertion of LMA between teeth until LMA deemed to be correctly placed & cuff properly inflated.
    - A maximum of 3 attempts allowed.
    - Any change in size of device will also be considered as an attempt.
    - If after three attempts of LMA placement, the criteria for successful placement of LMA are not met with, it will be

considered as failed placement. Need for the change of type of airway device will also be considered as failed placement

3. **Ease of insertion -** The Ease of insertion as graded by the anaesthesiologist inserting the device which will be graded as easy=1, moderate=2, difficult=3 and impossible=4

4. No. of attempts of gastric tube placement-Correct position confirmed by inflation of air & epigastric auscultation or aspiration of gastric contents.
5. Manipulations done during insertion - Any manipulations done during insertion of the LMA will be noted down like gentle withdrawal with advancement of the LMA, lateral rotation of LMA, chin lift, jaw thrust, head extension, neck flexion or change of size

6. Haemodynamic parameters – Heart rate(HR), Non invasive BP(NIBP), Saturation (SpO_2) will be recorded at 0/1/5/10/15/30 minutes starting from induction.

7. Respiratory Parameters – Expired Tidal Volume, Peak Pressure, Plateau Pressure and EtCO2 will be recorded at 0/1/5/10/15/30 minutes intervals starting from induction.

8. Complications- At the time of removal of LMA, any staining of the LMA with blood will be noted. Number of episodes of desaturation i.e., SpO_2< 90% will be noted down, the patients will be mask ventilated with 100% oxygen till optimal SpO_2 level is reached (95%).

Patients will be followed up for 12 hours after the surgery for complaints of sore throat, dysphagia and dysphonia. Sore throat will be rated on Numerical Rating Scale (NRS 0-10) by asking the patient verbally about the intensity of throat pain, (0- no pain, 1-3- mild pain, 4-6- moderate pain, 7-10- severe pain) during the follow up in post anaesthesia care unit. A score of more than 4 on NRS will be considered as sore throat.

STATISTICAL ANALYSIS-

Data will be described in terms of range; mean ±standard deviation (± SD), median, frequencies (number of cases) and relative frequencies (percentages) as appropriate. Comparison of quantitative variables between the study groups will be done using ANOVA or Kruskal-Wallis Test with post hoc Tukey's. For comparing categorical data, Chi square ($\chi 2$) test will be performed. A probability value (p value) less than 0.05 will be considered statistically significant. All statistical calculations will be done using (Statistical Package for the Social Science) SPSS 21version (SPSS Inc., Chicago, IL, USA)statistical program for Microsoft Windows.

Sample size calculation-

The objective of the study is to compare oropharyngeal leak pressures in I-Gel, AuraGain and ProSeal in laparoscopic surgeries in obese patients. The formula used is as under:

The formula used is as under:

$n = (\sigma 12 + \sigma 22) (Z\alpha + Z\beta)^2/(m1 – m2)^2$

Where,

$Z\alpha$ = Value of standard normal variate corresponding to α level of significance (1.96)

$Z\beta$ = The standard normal deviate for desired power (2.326)

m = Average

σ = Standard deviation

Assumptions:

From the study conducted by meenakshi sumadevi pradeep et.al. [6]

Mean Group (m1) = 25.17

Mean Group (m2) = 29.63

Coefficient of variation = 150%

Standard deviation Group (σ1) = 3.24

Standard deviation (σ2) = 3.56

With the above assumptions the sample size for 95% confidence level & 99% power works out 21 in each group. This number has been increased to 25 per group **(a total of 50)** to allow for a predicted dropout from treatment.

7.3 DOES THE STUDY REQUIRE ANY INVESTIGATIONS OR INTERVENTIONS TO BE CONDUCTED ON PATIENTS OR OTHER HUMANS OR ANIMALS? IF SO, PLEASE DESCRIBE BRIEFLY.

No

7.4 HAS ETHICAL CLEARANCE BEEN OBTAINED FROM YOUR INSTITUTION IN CASE OF 7.3?

Yes, Attached herewith

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PROFORMA

S.No	Group	Date of surgery
MRD No.	Type of LMA	Duration of surgery
	Size of LMA	

Demographic data

Age/Sex	
ASA Grade	
Height	
Weight	
BMI	
Neck circumference	
MPS	
Thyromental distance	
Mouth opening	

Comorbidities

DM	
HTN	
OSA	
COPD	

CRITERIA FOR SUCCESSFUL PLACEMENT

Parameter	**YES**	**NO**
Visible chest rise		
Bilaterally equal chest auscultation		
Appearance of a square waveform $EtCO_2$		

Signature of Candidate **Signature of Supervisor**

Oropharyngeal Leak Pressures (cm H_2O):

Before pneumoperitonium	After pneumoperitonium

Successful placement: Yes/No

Successful placement in first attempt: Yes/No

Insertion attempts:

Insertion time:

Any change in the size of device required: YES / NO

If yes, Size of the device:

Any change in the type of device : YES /NO

Any manipulations done to adjust LMA: YES/NO

If yes, mention the manipulation:

No. of attempts of gastric tube placement:

EASE OF INSERTION OF LMA

1) Easy	2) Moderate	3) Difficult	4) Impossible

HAEMODYNAMIC PARAMETERS

Vitals	HR (/min)	SBP(mmHg)	DBP (mmHg)	SPO_2 (%)
Baseline				
Induction				
1 min				
5 min				
10 min				
15 min				
30 min				

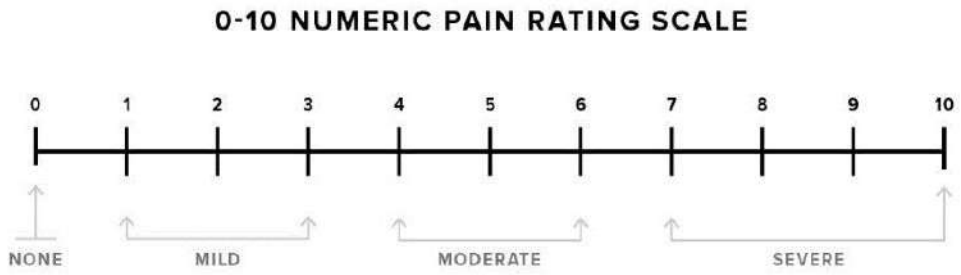
RESPIRATORY PARAMETERS

Vitals	Expired Tidal Volume	Peak Pressure	Plateau Pressure	EtCO2 (mmHg)
Baseline				
Induction				
1 min				
5 min				
10 min				
15 min				
30 min				

COMPLICATIONS

		YES	NO
Desaturation episodes (SpO_2 less than 90%)	Number of episodes: ____		
Blood staining			
Dysphagia			
Dysphonia			

SORE THROAT



INFORMED PATIENT CONSENT

Date: _____

I…….D/o, W/o, S/o……..…… am willing to participate in the study **"COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS"** The procedure with its complications has been explained to me in local vernacular language. I have fully understood that no special tests and extra expenditure in any form, merely for the purpose of thesis is being carried out. I am free to opt out the study any time without assigning any reason.

……. ……
Signature of the Witness Signature of the patient

Name:

Signature of Candidate **Signature of Supervisor**

मरीज अनुमति फार्म

तिथि _____

मैं _____ पत्नी/पुत्र/पुत्री _____

निवासी _____

इस शोधकार्य "**COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS**" में भाग लेने के लिए सहमत हूँ। मैं इस शोधकार्य में भाग लेने के लिए अपनी स्वेच्छा से तैयार हूँ। मैं पुष्टि करता/करती हूँ की यह स्वीकृति देने के लिए मुझे कोई आर्थिक प्रलोभन नहीं दिया गया और न ही दबाव डाला गया है। मुझे इस शोधकार्य का उद्देश्य स्पष्ट कर दिया गया है और मुझे यह विश्वास है की यह विज्ञान और मानवता के लाभ के लिए है। मुझे इस शोधकार्य में होने वाले जोखिम के बारे में समझा दिया गया है और मेरी समझ में यह जोखिम बहुत मामुली है।

मैं इस शोधकार्य में भाग लेने के सम्बन्ध में किसी भी समय अपनी अस्वीकृति व्यक्त कर सकता/सकती हूँ और मेरे अस्वीकृति व्यक्त करने का मेरे इलाज पर कोई प्रभाव नहीं पड़ेगा।

_____	_____
गवाह के हस्ताक्षर	रोगी के हस्ताक्षर/अंगूठे का निशान
नाम:	नाम:

_____

अन्वेषक के हस्ताक्षर

_____

विद्यार्थी के हस्ताक्षर

ਮਰੀਜ਼ ਰਜ਼ਾਮੰਦੀ ਫਾਰਮ

ਮਿਤੀ_____

ਮੈ_____ਪਤਨੀ/ਪੁੱਤਰ/ਪੁੱਤਰੀ_____

ਵਾਸੀ _____

“COMPARATIVE EVALUATION OF OROPHARYNGEAL LEAK PRESSURES DURING PLACEMENT OF I-GEL AND AMBU AURAGAIN IN OBESE PATIENTS” ਤੇ ਚਲ ਰਹੀ ਖੋਜ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਰਜ਼ਾਮੰਦ ਹਾਂ। ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਮੈ ਆਪਣੀ ਮਰਜ਼ੀ ਨਾਲ ਤਿਆਰ ਹਾਂ। ਮੈ ਇਹ ਦਸਣਾ ਚਾਹੁੰਦਾ ਹਾਂ/ ਚਾਹੁੰਦੀ ਹਾਂ ਕੇ ਇਹ ਰਜ਼ਾਮੰਦੀ ਦੇਣ ਵਾਸਤੇ ਮੈਨੂ ਕਿਸੇ ਵੀ ਤਰਾਂ ਦਾ ਲੋਭ-ਲਾਲਚ ਨਹੀ ਦਿੱਤਾ ਗਿਆ ਅਤੇ ਨਾ ਹੀ ਕੋਈ ਦਬਾ ਪਾਇਆ ਗਿਆ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਦਾ ਮਨੋਰਥ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਭਰੋਸਾ ਦਵਾਇਆ ਗਿਆ ਹੈ ਕੇ ਇਹ ਖੋਜ ਵਿਗਿਆਨ ਅਤੇ ਮਾਨਵਤਾ ਦੀ ਭਲਾਈ ਲਈ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਵਿਚ ਹੋਣ ਵਾਲੇ ਖਤਰੇ ਬਾਰੇ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ ਅਤੇ ਮੈਨੂ ਇਹ ਯਕੀਨ ਹੈ ਕੇ ਇਹ ਖਤਰਾ ਬਹੁਤ ਮਾਮੂਲੀ ਹੈ। ਮੈਨੂ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਦਾ ਢੰਗ – ਤਰੀਕਾ ਸਮਝਾ ਦਿੱਤਾ ਗਿਆ ਹੈ।

ਮੈ ਇਸ ਖੋਜ ਕੰਮ ਵਿਚ ਹਿੱਸਾ ਲੈਣ ਬਾਰੇ ਆਪਣੀ ਰਜ਼ਾਮੰਦੀ ਕਿਸੇ ਵੀ ਸਮੇ ਵਾਪਸ ਲੈ ਸਕਦਾ ਹਾਂ/ ਸਕਦੀ ਹਾਂ ਅਤੇ ਮੇਰੀ ਰਜ਼ਾਮੰਦੀ ਵਾਪਸ ਲੈਣ ਦਾ ਮੇਰੇ ਇਲਾਜ ਤੇ ਕੋਈ ਅਸਰ ਨਹੀ ਹੋਵੇਗਾ।

_____ _____

ਗਵਾਹ ਦੇ ਹਸਤਾਖਰ ਮਰੀਜ਼ ਦੇ ਹਸਤਾਖਰ

ਮਿਤੀ_____ ਮਿਤੀ_____

ਪਤਾ _____ ਪਤਾ _____

_____

ਨਿਰੀਖਕ ਦੇ ਹਸਤਾਖਰ

_____

ਸਿਖਿਆਰਥੀ ਦੇ ਹਸਤਾਖਰ